UNITED STATES OF AMERICA

DEPARTMENT OF DEFENSE

ARMED FORCES EPIDEMIOLOGICAL BOARD

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MEETING

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THURSDAY,

DECEMBER 11, 1997

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The meeting was held in Room 3092, Building 40, Walter Reed Army Institute of Research, Washington, D.C. at 0745 a.m., GERALD F. FLETCHER, M.D., President, presiding.

PRESENT:

COL MARTIN CRUMRINE, Institute Director
GERALD F. FLETCHER, M.D., President
COL VICKY L. FOGELMAN, USAF, BSC, AFEB Executive Secretary
DR. JIM ALLEN, Member
DR. BAGBY, Member
PROFESSOR SUSAN BAKER, Member
DR. JAMES CHIN, Member
LTC ROBERT F. DeFRAITES, Member
LTC RUSS EGGERT, Member
DR. L. JULIAN HAYWOOD, Member
DR. RICHARD JACKSON, Member
DR. JUDITH LaROSA, Member
CDR WAYNE McBRIDE, Member
COL FRANCIS L. O'DONNELL, Member
DR. DENNIS M. PERROTTA, Member
DR. POLAND, Member
DR. ARTHUR L. REINGOLD, Member
DR. ROSEMARY SOKAS, Member
DR. CLADD STEVENS, Member
LCDR TEDESCO, Member
LTC DON THOMPSON, Member
CAPT DAVE TRUMP, Member

PRESENT (Continued):

DR. RONALD J. WALDMAN, Member
COL WARDE, Member
DR. NEIL WEINSTEIN, Member

CPT CLARK, Speaker
COL JOHN GARDNER, Speaker
LTC MARK V. RUBERTONE, Speaker
LCDR MEG RYAN, Speaker
COL JOSE L. SANCHEZ, Speaker

ALSO PRESENT:

LTC PAUL AMOROSO
MR. DAUGHTRY
COL PHIL DINIEGA
COL EITZEN
COL ENGLER
COL JOEL C. GAYDOS
CAPT GREG GRAY
CDR KEVIN HANSON
DR. ROBERT MORROW
MAJ ROBERTO NANG
MS. PENNY PENNINGTON
CDR RENDIN
CDR TRENT
DR. THEODORE F. TSAI
MR. WALTER WOODS

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(0752 a.m.)

WELCOME/ADMINISTRATIVE ANNOUNCEMENTS

MODERATOR FLETCHER: I'll thank everyone for coming this December day. It's actually clear weather here. They cleared this for us. It's only a bit of rain. There are no freezing temperatures predicted for the weekend.

Let me remind you I think this meeting meets always for an interchange with our colleagues in the military. I think our Armed Forces Board, we always learn a lot from our colleagues in the military. I think it's important for us to be back and working with each other.

I think we have been able to have a number of our official recommendations go up the chain of command. Maybe Colonel Fogelman can tell us sometime of their responses to these. Sometimes we don't know exactly what happened to some of these recommendations, but it's important what we do anyway, actually getting things, getting writing, approved, so forth.

Today we are going to begin, of course. Colonel Martin Crumrine has taken command of this facility. I should thank him for

allowing us to meet again. Would you like to add a few comments this morning?

COL CRUMRINE: Well, on behalf of the staff of the Walter Reed Army Institute of Research, again welcome to this rather august group. It's an honor to have you here. Whatever we can do to make your stay pleasant and more productive, let us know.

I have to give you a minor apology, which is beyond my control, for the condition of the grounds between here and the Malone House. That was a construction project that we had not anticipated until about a month ago. It's ongoing, and we're dealing with it like you are. So come around the building. Come in the side doors or the front doors. And you'll just have to deal with it like we do. Again, that was not planned for you.

My predecessor, for those of you who wonder where Ernie Takafugi went, is now the Deputy Commander of the Medical Research and Materiel Command and will have an official change of command here next week, but I am assigned right now into the job.

I just on behalf of the WRAIR again want to welcome you. It's good to see some old

friends, some faces that I can now put with names on the other end of telephones. And those of you whom I haven't met, I hope to in the next few weeks.

Again, welcome and thank you. Unfortunately, I need to go do other commander business right now. Let me take this time to say some of that commander business I have to do is rather unfortunate, and it is one of the topics you're dealing with.

We have three soldiers that we're processing through various administrative actions for alcohol abuse. And that is not a problem that's going away. So it is a timely topic. And while it's unfortunate, if there's anything you can do to help us solve or at least address the problem better than we are now, it would be greatly appreciated.

Also being a participant in the swine flu vaccination several years ago, I understand the significance of this new strain of influenza that people are describing. And we may not get to that stage, but I think we need to make careful analysis so we make the right decisions on that.

So, with that, I want to leave you and

say thank you very much. Have a nice meeting.

MODERATOR FLETCHER: Thank you very much.

I just want to let you know one of our subcommittee subgroups is leading with the alcohol issue. And I think this is most appropriate, as you stated, such as the data that comes out in the New England Journal today about one thing beneficial to all Americans, which is I'm not sure how that's going to make the public respond in many areas. Judy, would you like to address that also?

DR. PERROTTA: If one's good for --

MODERATOR FLETCHER: Colonel Fogelman?

EXECUTIVE SECRETARY FOGELMAN: Yes. I'd like to say good morning to all of our Board members, consultants, and invited guests. I hope everyone's accommodations are suitable. If not, please let me know or Ms. Ward. We can make adjustments if necessary.

I would like to say Dr. Mazzuchi, the Deputy Assistant Secretary of Defense for Clinical Services and Health Affairs, fully intended to be here this morning but called yesterday and said that there was another issue that was fairly urgent that he had to attend to.

I will certainly convey everything that happens on the Board to him. He's very interested in the work and has been very supportive of the work. He sends his regret. He would certainly like to be here but cannot.

I would like to advise everyone that this is an open meeting. There probably are members of the press here. So please temper your comments accordingly. It doesn't mean you can't say what is your pleasure. Just be aware that there are members of the press here.

As far as the press is concerned, before you go to press with an issue, I would appreciate it if you would talk to the speaker and validate what notes you have taken, make sure that what you're saying is an accurate account of the events that took place or what the speaker said.

We have a very aggressive schedule over the next few days, extremely aggressive. In fact, the Infectious Disease Committee schedule has added two new topics, which you may not be aware of. So we ask the committee chairs if they could try to keep their groups coordinated and on time.

The Environmental Health and Health

Maintenance Committees will be combined tomorrow for a number of reasons, to discuss several issues together. I have a tentative schedule here, which I will give the subcommittee chairs. And you can obtain the schedules from them.

Also, tonight a number of people have expressed an interest in possibly going out to dinner on sort of an informal basis. I will circulate a sheet here. Please put your name down and "Yes" or "No" so we can get a count of who would like to go. I would appreciate it.

Tomorrow for lunch, we will have box lunches for those who want them. So before 10:00 o'clock, you need to tell people if you want a box lunch and pay for it.

Today it will be lunch on your own. However, Major Fisher has very nicely reserved about 50 seats in the Malone House. We have a little area petitioned off. So it might be a good idea if you'd like to go there. There are other eating facilities on the campus as well or you could go back to your rooms, but she has reserved this area if you're interested.

Right after lunch today, there's a slight change in the schedule. Dr. Fletcher will give a very brief talk on issues related to

global warming.

MODERATOR FLETCHER: Global disease burdens.

EXECUTIVE SECRETARY FOGELMAN: I'm sorry. Global disease burdens. Sorry about that. Very brief talk. Add that to your agenda. And it will push the talk back after that by about 10 or 15 minutes.

Otherwise I think we're about ready to begin. We have today three people involved in the first topic, which is the follow-up to the JE vaccine booster study issue that was brought up about a year ago. The Board had asked that the military go out and do a follow-up to see what types of serologic titers we would see in people who had received boosters.

Today we have with us: Lieutenant Colonel Bob DeFraites, who has been a medicine staff officer for the Army Office of the Surgeon General; Commander Wayne McBride, who has been a medicine staff officer for the Bureau of Medicine and Surgery for the Navy; and Dr. Ted Tsai, the Assistant Director of Medical Sciences for the Division of Vector-Borne Infectious Diseases at CDC for Fort Collins.

Would you stand up, Dr. Tsai? It was

his lab that actually ran the tests for both of the studies we're going to talk about. So he would be leaving right after the presentation. If you have specific questions for him about the laboratory issues, please ask him during the briefing. He will not be standing up to give a formal talk, but he will be available for the questions.

So first on the agenda will be Lieutenant Colonel DeFraites.

JE VACCINE BOOSTER STUDY FOLLOW UP

LTC DeFRAITES: Hi. Good morning, everybody. Again, it's my pleasure to address the Board. Our purpose this morning is twofold. My part is to review the state of knowledge on the Japanese encephalitis vaccine up through the Board's recommendation last year that a three-year booster was acceptable, that delaying a booster to three years was acceptable, then to present the results that have occurred in the last year based on a Navy and Marine Corps study.

Commander Wayne McBride is going to present that. I'm assuming he's going to do that if he comes back to the room. If anyone sees him, please let him know that he is after me. If not, I will do the best I can to present.

And you'll see in your packet -- I don't have his slides, but you'll see that you have a handout that has Japanese encephalitis vaccine as the title. And I'll use that when I think we can get through it.

Let's just start with my slides, first of all. The BIKEN Japanese encephalitis vaccine was licensed in the United States for general use in December 1992. Prior to its licensure, we had embarked in the Army -- actually, it was an Army and Navy collaborative study -- to develop some knowledge about the immunogenicity and persistence of antibody of the vaccine.

This study was performed at Schofield Barracks, Hawaii. And this is in the era before we had advanced, where applicable, support and shows the creativity of us out here at Schofield Barracks, the JE shots started. And you see we're very keen on making sure that got reported in the shot records.

Next slide, please. This is the soldiers of the 25th Infantry Division who participated in the study.

Next slide, please. I'll just run real briefly through what the study was all about. We started with 538 soldiers. Our

purpose was really to do a lot consistency comparison and to look at two different dosing regimens.

For today, the important part is the fact that we started with 538. And we drew blood for antibody titers at days 60 and 180 for the first part of the study.

This is the vaccine. Actually, this lot was Lot Number 30 produced in, this one says, '94, one of the comparison lots. At the end of 6 months, 26 weeks, 98 percent of those who received 3 doses -- it didn't matter which of the 2 dosing regimens you received, but after 3 doses, 98 percent had antibody of a neutralizing antibody titer again run a CDC of one to 10 or greater.

In comparison to that, previous studies using just two doses in American adults, both, one military study and one civilian study, after about anywhere between 6 months and 12 months, only 29 to 67 percent of adults had detectable antibody at the one to 10 level after 6 months. So it did seem like this third dose was necessary.

Our study was continued. Again, I showed you the data at six months. Our study was

continued for an additional 24 months as part of the original study. We had antibody titers in this original cohort out to 24 months.

An additional part of this study was a booster trial, that we gave a booster at 12 months originally. Because we didn't have the antibody titers, we didn't know how immunogenic it was. And originally the vaccine called for a booster at one year.

We gave a booster to about 252 of the original 500 in the cohort. So we had about 286 soldiers who didn't receive a booster. Those were the people we looked at at 24 months and then later on a small group of 39 at 36 months to see the persistence of antibody after 3 doses of this vaccine without a booster. That part of the study was finished in January of '93. You heard that data presented last year.

In graphical format, this is the study again, the original study with three doses, great antibody response at 12 months. Almost 100 percent still had detectable antibody at 12 months with a fairly nice geometric mean titer of neutralizing antibody.

You can see here for these soldiers who were boosted the great effect of the booster

at 24 months. They still had very high titers. It was a small group, again, as I mentioned, that we did not boost. Practically all of the soldiers who had received a three-dose series, even without a booster, still had antibody at 24 months. And the majority of them had antibody at 36 months.

Of the 39 soldiers that we had who were still in the military 3 years after we did the study, of the 39, 37 of them still had detectable antibody at the level of one to 10 or greater. That's what the original Army study showed.

Then last year the Board when asked if it was acceptable for the booster timing to go from two years to be delayed to three years or more, the Board recommended that that be acceptable. However, the Board called for more data. And that data was collected this past year.

Is Wayne here yet? Here he comes. And here's Commander McBride.

CDR McBRIDE: Well, let me catch my breath for just a moment.

LTC DeFRAITES: Wayne, I've already kind of given the background. And I don't know

where your slides are. So I would start with methodology.

CDR McBRIDE: Thanks. Good. Thank you.

Well, good morning. I appreciate your patience here. I was going to say we had some difficulty, but I wonder if we still do. When I prepared my presentation, as some of you know, I had it in a version that apparently was not supported by the laptop they have here. And the staff was kind enough to try to make some last-minute changes to accommodate that. I think we'll be okay. So I'll just catch my breath for a second while they put that up.

Good. Thank you. If you could go ahead, please, to about Slide 3 or 4? I think Dr. DeFraites has gone over some of the background and reviewed the work that had been done previously. And, as may have been indicated before I came in the room, what I'm going to share with you this morning are the results of a serosurvey that was done on a number of Marines over the last year.

This work was really done by some folks at the Preventive Medicine Unit Number 6 at Pearl Harbor. We kind of passed through the

collaborator slide, but it's on your handout.

And I wanted to give appropriate credit to Dr. Beecham and Dr. Yund and then other participants in this study that couldn't be here today. So I was asked as someone within the Beltway here who is somewhat familiar with their work to present it. And I hope it will be meaningful to us today.

The Marines that participated in this study were selected from three sites: from the activities at Camp Pendleton, and then from the Marine installations in Hawaii: one at Cape Kaneohe Bay and Pearl Harbor.

The records were reviewed for those individuals who had received or had completed the three-dose basic Japanese encephalitis vaccine series. And immunization dates and other data were recorded on a survey form.

Next slide, please. Once the serum was drawn and separated, it was sent to Ted Tsai, Dr. Tsai, at CDC in Fort Collins, where the determinations were made for the antibody titers and the data was analyzed in EpiInfo.

Next slide, please. Could you skip to the next one? And then we'll come back. Thank you. Now, this is an array of the results that

are expressed by the time the serum was drawn relative to when the basic series was completed. Let me explain.

There were Marines who had received and completed the basic three-dose series between one and 12 months before their serum was drawn, between 13 and 24 months, between 25 and 36 months, and so forth. And then the results of their serum determinations are indicated on the left. The JE titers are expressed there.

Now, this also includes about seven personnel who had also received a booster subsequent to having completed the three-dose series. We initially prepared some slides with data showing what the results were. But then we realized that some individuals had received a booster dose.

And so at the last minute yesterday, we did another analysis of the data and took out those individuals who had had a booster dose. And, if you could, Major Fisher, go back to the slide just prior to this? So the *n* goes down. Go to previous, if you will. And the *n* goes from 75 Marines to 68. And let's pause here for just a moment.

What this shows are those Marines who

had their blood drawn one to two years after their basic series was complete, again two to three and so forth and then what the results are, who had titer levels in the protective range, which is expressed as equal than or greater to one to ten.

We see that for those individuals who had received the vaccine that had completed the basic series in the last few years, their titer levels, those with protective levels are relatively few. And as we go out to three to four, then certainly at four years and greater, the number of subjects or vaccinees with a protective titer level really increases. And these are again people without booster doses.

Let's go to the two slides down, if you will. And we'll pursue this. This was expressed in a little table format that sets this up for some other slides that I wanted to talk about.

Again, this is years from initial series completed. And then we see the percentage of those individuals who had titers in the protective range. Also, an analysis was done to see if this was a significant trend. And those who had received the further back one had

received the basic doses that completed the JE series, the greater the percentage of vaccinees that had protective levels.

Next slide, please. And this is expressed by the year of the initial series. When did they get it? Those who had recently received it, of course, there were four in this study that none of them had demonstrated a titer level in the protective range. And those that received their basic series some years ago again were more likely to show a titer in the protective range.

Next slide, please. Well, we said: What would be the effect of something like getting another vaccine after completing the basic series? And would that have shown a difference in their titer results?

So from the 68 vaccinees that were studied that had not received a booster dose of JE, what about those who had not received a yellow fever? And those who had received a yellow fever vaccine subsequent to completing the JE series were removed from the pool.

And we see that there continued to be a trend, showing again that those who had received their vaccine some time ago were more

likely to have a protective level.

Next slide, please. Well, what about the concept of perhaps some natural boosting? What about those Marines that might have been back into the endemic area?

We took those that may have been back in the endemic area, and we removed those from the set and then looked at the data. And again we see, albeit the numbers are very low or few, the trend still persists. And it's quite interesting.

The next slide, if you will. Well, let's summarize what our findings were. And you have those in front of you. Certainly the first point was that as we looked at the data, there was an unexpectedly low percentage of vaccinees that had titers in the protective range who had received the basic series.

And, again, of those who had received it just a couple, 2 to 3 years previously, it was a very low level, about 27 percent. And those who had received the JE series 3 to 4 years, again, it's a rather low, startlingly low, level of 33 percent.

Next slide, if you will. What about those who had received it some time ago and had

not had the benefit of a booster dose? Even though the numbers are low, six of seven of those who had completed their dose over four years ago, before their serum was drawn, had protective levels.

Now, I'll just acknowledge the results of those who had received a booster dose or among a group of those who might have received a booster dose. At 2 to 3 years, their numbers were, of course, higher at 49 percent. But our interest, of course, today was to look at those who had received simply the basic series because we wanted to find out if we could endorse our recommendation to keep it at three years, two years, or to three years for when they should receive their booster dose.

Let's go to the next slide, please. Well, this really brings a number of discussion points to explain what I think were kind of unusual findings.

Certainly one thing that might be considered, is there some laboratory error that could contribute to these results? Well, each of the assays were repeated by the same lab again and 94 percent concordant. So it wasn't felt that laboratory error would have played an effect

in this.

How about specimen handling? There are some constraints you know with the terms of specimen handling, freezing, and these things. This was looked at carefully and not thought to be a problem and no evidence of contamination.

Well, the concern about what about vaccine potency, there are two concerns here. One would be perhaps some degradation because the way the vaccine was handled or the way it was constituted and then kept.

It's in a ten-dose vial. It's constituted with some sterile water, I believe. And then the intent is to immunize people from that ten-dose vial within several hours, eight hours. But occasionally people might have kept the vial in the refrigerator and then used additional doses later.

This is always a thought that we have to ask ourselves in real life. We can't assess the effect of that exactly. We have to just acknowledge that that could be a possible concern.

Improper administration techniques. JEV is administered subcutaneously. And we know that the majority of the other immunizations that

we give in the military are administered intramuscularly. And we wonder: Perhaps could the route of administration or the method it was given cause these findings or contribute to these unusually low titer levels?

We have to acknowledge that perhaps it has. One of the collaborators, Scott Sherman out at Camp Pendleton, went back to some of the vaccinees and asked them if they could recall how they had received the JEV series some years prior and asking them some certain questions.

This, of course, is not terribly scientific, but from his brief review of several people who had been vaccinated, it was very consistent that they had probably received it intramuscularly by the way they had described to him how they had received the vaccine series, suggesting, of course, that many of these people may have received it improperly.

Well, one of the concerns we have is: Is there a possibility that the vaccine potency has diminished in recent years? If we remember the results that we've shown that those who have received the vaccine in '92 and '93, their potency, their titer levels were more significant. And could the vaccine potency have

diminished in the recent years? That's a real concern.

Dr. Tsai has considered that and talked to the FDA and was assured that each vaccine lot as it's released is tested and compared against the standard. And the information that we have suggests that vaccine potency has remained the same or certainly has not diminished. I may ask Ted to comment on that further in a moment. From my understanding, that's not been a concern.

The last, of course, point would be real world versus study environment. Bob's come back to join me at the podium. The work that was done with the Army a few years ago was, as we may know, in a I think fairly controlled situation.

These were a select group of people that had been administered the vaccine under some controlled circumstances. This population had been followed carefully. And then, of course, we saw some very nice numbers from them.

This serosurvey of the Marines, these were drawn from different sites, different places. Different people had administered the vaccine over different periods of time. A lot of other things could have entered into this.

Let's show the last slide, please. And then we'll open this to discussion. The recommendations that emerge from our look at this serosurvey, certainly this suggests the need for perhaps a more comprehensive study tracking the JEV, the JE antibody levels after immunization.

We have looked at the FDA. We'll comment about that in just a moment again about possible alterations in potency. There does not appear to be from the information we have that that's an issue.

Well, certainly there's a need we think to issue a memorandum or a letter to the Services drawing attention to the importance of proper administration of this vaccine and the proper handling of the vaccine as well since this is something certainly that we're probably going to be doing in response to the study that we've done. And that will be I think meaningful to our people in the field to remind them about the specifics about administering JEV. And hopefully that will enhance the antibody response in the future.

The other thing that Dr. Tsai and I spoke about just this morning was a recognition that we have a number of Marines out here who

have demonstrated relatively low titers or low protective titers to the JEV, suggesting that we may need to look at going back and reapplying the vaccine to some of these people or seeing what the responsiveness will be after the boosting dose and seeing if just the booster will be enough to bring them into protective level. But certainly these are some of the things that we've considered as responses to the work that we've done.

Bob, did you have any comments before we open it to discussion?

LTC DeFRAITES: I wanted to just reiterate this point about the administration. Could you turn the slide projector? I've got a couple of slides, if we could turn this off for a second or just put the lens cap on, of the why a Marine might remember a subcutaneous administration of a vaccine.

This is Dr. Sanchez giving a subcutaneous. This is the JEV vaccine. You can see that giving a subcutaneous with a triceps fold with a short needle, you give the dose at somewhat of an angle.

And this is sort of the overhand technique again. I mention sort of a skin fold

in the triceps and giving the dose at an angle. I think, as Wayne alluded to, probably more commonly in a shot line or as doses are administered, the dose is given straight in with a long needle and given intramuscularly.

What effect this might have on the immunogenicity I don't think we really know. That's the only thing I had.

CDR McBRIDE: Are there comments or questions, please? Yes?

DR. SOKAS: I was wondering if you had data on where they got their shots from when you were collecting this because unless the first cohort that people for four years or more go who got it as part of the research group, it wouldn't explain the real world versus research difference in the administration.

LTC DeFRAITES: None of these would have gotten the dose in our study.

DR. SOKAS: In your study?

CDR McBRIDE: This was a separate population of Marines. And the work that Bob did, they were Army people.

DR. SOKAS: So the question is: Why did the people who got their shots four years ago take than the ones who got it more recently? Is

there some systematic difference in administration or training of the health care people or what?

CDR McBRIDE: That's an excellent question. One thought that comes to mind may be that since it was relatively new vaccine, perhaps people were more attentive to the proper administration. In ensuing years, perhaps they've been less careful about administering the vaccine in a proper way. That's just a thought.

DR. SOKAS: But if you knew where they were getting immunized, you could look for differences between clinics to see if some clinics are doing better and others are doing worse.

CDR McBRIDE: That's a good question. Dr. Sherman has gone back and looked at the data and looked to see where these people were initially vaccinated. And there was no trend there. They were from all over, from several, five or six, different sites from among the population that was studied.

MODERATOR FLETCHER: Another question? Please identify yourself.

DR. CHIN: Dr. Chin.

A question about manufacturer and

vaccine lot and assignment of lot and so forth.

DR. TSAI: Well, actually, Walter Woods, representing Pasteur Merieux Connaught, is in the audience as well. I don't see Lou Markoff from CBER. Is someone from his laboratory here? Well, perhaps Walter could comment on Dr. Chin's question.

MODERATOR FLETCHER: Please identify.

MR. WOODS: Walter Woods, Pasteur Merieux Connaught, U.S. I worked closely with Bob in obtaining the license for this vaccine back in 1992 and was the primary interface with CBER.

The lot size definitely did not change. The manufacturing hasn't changed. They visit and inspect them very thoroughly every year. So there's a very emphasis on being certain that we maintain the same manufacturing controls that we had during the licensing process.

The potency of the vaccine has been analyzed. As a matter of fact, the effect in this case has been a straight line in the level of potency over the years since licensure.

I would like to comment on a couple of things. That is, I'm not sure in the laboratory

if we ran any control samples of the serum four years ago versus the studies we're doing now as a control, which might be very important to take a look at, even though you may have concordance in the days as cumulative assays change over the years and things can happen in the laboratory where you may not see that. That doesn't explain the percent, but that's one point.

The second point I wanted to make is that subcu versus the IM is a very, very critical immunization factor. The Japanese showed that, demonstrated that when the vaccine was first developed. It's very critical.

MODERATOR FLETCHER: Thank you.

Dr. Poland?

DR. POLAND: You talked about potency, its ability at the time of lot release, but how about with time? I realize we don't know that there were delays between when the vaccine was released or the time interval between when the vaccine was released and when it was used, but do you know anything about the stability and potency of the vaccine with increasing shelf life?

MR. WOODS: It's sort of like the FDA. I found out about this yesterday. I will be taking a lot deeper look at this. I do know that

this is building data that we do have. With the potency over time, there's nothing there that would cause us concern.

DR. POLAND: You say that the Japanese have shown that the route of administration was critical. Was it in the same direction as these findings; that is, giving it IM led to decreased immunogenicity over time?

MR. WOODS: As I mentioned before, I really didn't have time to pull out all of the data. I know those studies were run originally to support the Japanese licensure.

MODERATOR FLETCHER: Dr. Chin?

DR. CHIN: Just a follow-up to my initial question. Can we assume that each year different lots are used?

DR. TSAI: Walter, can you answer that?

MR. WOODS: Well, there would be I'm sure different lots used, but it would really depend on the military's research and the military's logistical distribution of that vaccine.

COL ENGLER: Dr. Engler, Allergy and Immunology at Walter Reed.

I'm commenting on training and route

issues. It is a major problem since there are no DoD proficiency standards for minimum requirements for training or validating a knowledge base of people to deliver shots.

Our school for 23 years, most people now don't have the TDY funds and call us desperately for how to train. R.N.'s are not familiar with this information, the incidents, or its highlights.

I would just say a comment earlier. When a PI was designated to be responsible and involved in JEV delivery at early phases, I think everybody took a lot of care. It was carefully signed, and you carefully read what you were doing. And that's a lot different than when it gets thrown in with all the rest of the vaccines.

We in the national capital region have training sessions for the outlying clinics and repeatedly find that people don't know about different needle sizes and what the issues are for making sure they are correct.

DR. TSAI: One point on the vaccine administration. The volume of the vaccine delivered subcutaneously is unusually large. It's one cc, which is a large volume for subcutaneous administration. It's something that

I think one wouldn't normally encounter with other vaccines.

MODERATOR FLETCHER: Please identify.

CDR HANSON: I'm Kevin Hanson from USUHS.

Just a little background. The way this is given in Marine Corps units, it's really not given at an immunization clinic. It's given by unit medical departments typically in the unit spaces. So you have a very wide variety of junior Corpsmen.

It's not like these people give vaccines all the time. So it's quite conceivable that there are significant quality assurance things that may go on in this kind of a very diverse setting that these actions are given.

DR. TSAI: I was just going to make one more remark about the vaccine potency standards. In addition to the standards recommended by the Japan NIH to standardize vaccine potency in terms of mouse protection, the FDA before the vaccine was licensed in the United States put into effect other semi-quantitative standards for the quantity of the envelope glycoprotein in the vaccine, which is presumed to be the principal immunogen.

And it's based upon evaluating the degree of staining in a Western blot at the band for the expected position of the envelope glycoprotein. And from what Lou Markoff told me over the years, that semi-quantitative measure really hasn't changed.

So our evaluation of vaccine potency would suggest that it hasn't deteriorated since the vaccine's license.

MODERATOR FLETCHER: Dr. Reingold?

DR. REINGOLD: Yes. Can you tell us what the data are concerning what protective level is? Because I'm not sure I know what level's protective. It could very well be that it had been it happened to involve in the current military needs at least one additional dose of the vaccine.

DR. TSAI: Well, we generally accept the one to ten as the minimum effective titer, although if you passively immunize a mouse with antibody, some of them actually are protected at undetectable levels of neutralizing antibody.

So there may be some protection at a level even below one to ten. We generally accept one to ten as protective, although I think most people would prefer to see one to four or a

higher level.

MODERATOR FLETCHER: Other questions?

(No response.)

MODERATOR FLETCHER: Thank you very much.

EXECUTIVE SECRETARY FOGELMAN: Now, the Board will be asked to provide a recommendation at this meeting. We'll ask the Executive Council and each subcommittee to draw up a recommendation. Thank you very much.

(Applause.)

EXECUTIVE DIRECTOR FOGELMAN: Our next speaker is Captain Clark, Coordinator for Accession Medical Standards Analysis and Research Activity. She'll be talking about accession asthma standard: current policy issues. Dr. Clark?

CPT CLARK: Thank you and good morning.

ACCESSION ASTHMA STANDARD-CURRENT POLICY ISSUES

CPT CLARK: The study I'm going to discuss is being performed under the Accession Medical Standards Analysis and Research Activity. We're currently examining the accession process with respect to asthma.

Asthma is common and affects

approximately two to six percent of the American population. There has been a significant increase in the hospitalization rate, death rate, and overall prevalence of asthma in the United States over the last 20 years.

It is of vital importance to the military as active-duty persons are exposed to a variety of factors that exacerbate asthma, such as exercise, cold, dust, not to mention stress, smoke, fumes, and pure astygmine. Unknown environmental factors also play a role.

Next slide, please. Although it's been increasing today, asthma has been a problem in the past around the world. And in World War II, 30 percent of applicants were disqualified from military service. And two percent of those were for asthma.

In a British study, they predicted that if people enlisted in the Army with a history of childhood asthma in remission in their teens, 40 percent would do fine, but 25 percent would require downgrading of their duties, and 35 percent would be discharged due to asthma.

In Desert Storm, 500 Army soldiers could not deploy because of asthma. And of those that deployed, 200 had to be evacuated from the

theatre because of asthma. There is extensive cost and loss of military readiness associated with asthma-related illness, disability, and discharges.

Next slide, please. The prior Department of Defense directive governing medical accessions did not allow persons to access into the military with asthma symptoms after the age of 12.

This directive has recently been changed. The current disqualification, effective in August 1995, is asthma, including reactive airway disease, exercise-induced bronchospasm, or asthmatic bronchitis, reliably diagnosed at any age.

The directive also specifies that a substantiated history should be symptoms persisting generally more than six months. The results presented here are from data gathered after the change in the directive.

Next slide, please. Asthma in childhood is a significant but difficult to quantify risk factor for adult problems. This study was undertaken to evaluate the current process in the military of waiving some individuals with asthma to enter the Service.

And this quote from General Sternberg to the Army medical school graduating class of 1902 explains the purpose of studies like this well.

Next slide. The study goal was to perform a survival analysis comparing survival either by remaining on active duty or by remaining free of an asthma-related hospitalization or discharge of those waived for asthma with others.

Next slide. The cases where enlisted recruit applicants disqualified at the medical entrance processing stations who received a waiver for asthma and started training in 1995 or 1996. They were verified to have started basic training by gain files in the Defense Manpower Data Center, or DMDC.

Next slide, please. Controls were chosen from the gain files in 1995 and 1996. They started active duty in those years. The controls were matched to the demographics you see here. The matching criteria did have to be relaxed somewhat.

Next slide, please. In the analysis, the first endpoint was a failure to survive for any reason, including conditions that existed

prior to Service or EPTS, disabilities, and nonmedical conditions. These discharges from the Service were obtained from the active-duty loss files at DMDC.

The second endpoint that was used was an asthma-related EPTS discharge hospitalization or disability discharge. All losses were weighted equally in the analysis.

Next slide, please. These are the ages of the cases in the matched controls. The controls were matched to the cases, not to the overall population entering the military.

There were too few numbers in the Air Force. So they are not included in the overall analyses, but I will mention them later.

Next slide, please. Most of the cases in those controls were males. And listed above the bars are the total number in each group.

Next slide, please. They were predominantly white.

Next slide. This is the distribution of cases and controls by Service. And, again, it does not reflect the proportion of each Service making up the whole military. The cases were taken using accessible and useable data, and the controls were matched to the cases.

Next slide, please. This curve shows the experience of remaining in the Service for cases and controls. A hundred percent start on active duty in the left of the graph. And the vertical axis is the probability of remaining on active duty over time.

As time passes, some people are discharged for various reasons. The cases, the asthma waiver recipients, are not discharged faster than the controls. And at the end of the two-year period, similar proportions are on active duty. The numbers to the immediate right of the lines are failures out of the total numbers.

Next slide, please. For the Army, no differences were found in experiences for the cases and controls over time.

Next slide, please. The same can be said for the scrap of the Navy as for the Army on the prior slide.

Next slide. And likewise for the Marines, for which there was a smaller sample size.

Next slide. When the endpoint used was an asthma-related failure, such as an EPTS discharge, hospitalization, or disability

discharge, preliminary results based on small numbers of endpoints do suggest that those waived for asthma may experience asthma-related failures faster than matched controls.

Next slide, please. There were only 13 individuals waived for asthma by the Air Force that met the case definition. These 13 were similar with respect to age, sex, and race as the 368 cases used in the analyses. All of these 13 cases remained on active duty at the conclusion of the calendar year 1996.

Next slide, please. In this study, it was assumed that the data used had been properly recorded. Since not all waivers were captured but only those with complete information, it was assumed that known cases were similar to those with missing data and that one person's survival experience did not influence another survival time directly.

Next slide, please. This was an evaluation of what happens to those disqualified and then waived for asthma, not those truly with asthma.

Asthma outpatient morbidity, not examined here, has a significant impact on military cost and readiness. And information on

the severity of the disease is not available in the data sources we used for this analysis. And differences in survival for mild, moderate, and severe asthma cannot be determined.

Next slide, please. The study was really undertaken to examine the waiver process with respect to asthma. Almost 73 percent of the 1,014 with asthma existing prior to Service discharges in 1995 did not reveal their asthma before entering basic training.

As you can see, most of those receiving EPTS discharges for asthma in 1995 were never a part of the waiver process being evaluated. So even if the waiver process is perfected, asthma EPTS discharges of individuals whose asthma was never known to the waiver authority will continue.

Next slide, please. In conclusion, preliminary results show that the chance of remaining on active duty for someone coming into the military with a waiver for asthma is comparable to that of a matched control.

Statistical significance was achieved when testing for asthma-related discharges or hospitalization. The meaningfulness of this may become more clear as the study progresses.

The cases and the controls were only followed for two years. So differences in discharge rates beyond that are not shown. And also and probably most importantly, concealment of a history of asthma is a significant problem.

Next slide, please. The study is being extended to include more waived persons and longer follow-up. Next steps may include adjusting for other factors, such as body mass index, smoking, and job classification. Also, the frustrating problem of recruits concealing a history of asthma needs to be addressed.

Possibilities that have been discussed are asking all applicants to bring all available medical records with them, prosecution of the recruit or prosecution of the recruit's physician, or increasing the use of an improved screening test.

Next slide, please. And I just wanted to thank the Accession Medical Standards Working Group Steering Committee and the waiver authorities for their generosity with the waiver data.

MODERATOR FLETCHER: Thank you, Dr. Clark.

Let me ask you one question. The

exercise-induced asthma -- normal people can have wheezing when they exercise. Would you qualify this a little more? Were these people who really had their asthma diagnosed just when they were trained? The level of training, if it's higher, was it less likely to induce asthma? Would you comment on it?

CPT CLARK: I think I can comment on both ends of the spectrum. The diagnoses made of people that are applying to come into the Service at the military entrance processing stations are various ranges of specificity.

Some of them will just come in and say, "I have asthma," and that's disqualifying. Some of the physicians at the military entrance processing stations will go into more detail, asking them what age they had symptoms.

Some people think asthmatic bronchitis is not even a diagnosis. So there are varying degrees of specificity between the individual military entrance processing physicians examining recruits. And the waiver authorities also have a variety of specificity with which they call things asthma or not.

The DoD directive that I showed you is supposed to apply to all Services. Then certain

Services can become more specific. The Air Force has a more specific policy at their Office of Standards, which they say states specifically any wheezing, two, three episodes of wheezing six months apart, associated with an infection or not, or any two episodes of wheezing six months apart. And that's their diagnosis of asthma.

Once they come into the military in our basic training, whether or not they're called asthma or what criteria are used to say that they have asthma also varies. And people speculate that there are a lot of motivational issues in that also if someone comes in because they're having a difficult time keeping up with the physical training, they say they're short of breath, they say, "Oh, well, I maybe have wheezed when I was eight."

So, unfortunately, there are not strict definitions throughout the spectrum of the process.

MODERATOR FLETCHER: Dr. Engler?

COL ENGLER: Dr. Engler, Allergy and Immunology.

I just wanted to make a number of comments: one, on Desert Storm. Many of the patients who present back labeled with the

diagnosis of asthma on subsequent careful evaluation have vocal chord dysfunction, which is an entity that is largely not diagnosed by primary care physicians, does take an extensive amount of evaluation, has a number of complexities associated with it.

There's difficulty with that data. Just one of our people in our community is very aggressive in analyzing the data at Fort Benning. All of his asthmatics that deployed to Desert Storm completed their tour with no difficulty with maintenance inhaled steroids.

You really can't take World War II data because your treatment isn't adequate. Those asthmatics who got in trouble were ones that had hidden their asthma and were not adequately treated.

And I think what people fail to recognize is no matter how many standards you exclude, asthma really exists because 20 percent of the population is atopic.

As new-onset asthma does occur on a regular basis at any age, that's going to be difficult. You're not going to be able to process it. You're going to have a slew of experts and NIH guidelines, et cetera, to suggest

that this is a non-cancer.

And if you exclude the recruiter positions, which we deal with all the time, there are so many people who have wheezed at some time in their lives.

If you are going to have a serious problem with a volunteer Army recruiting, unless you give, like the Air Force, six months apart --

CPT CLARK: Right.

COL ENGLER: There is no perfect test. We use methylcholine challenge. Many people are positive for methylcholine challenge but you never have asthma in long-term epidemiologic studies if you don't know of the disease.

So it is a more complex issue, despite the attempts to try to make simple rules. And I think the issue of permanent treatment -- we have the problem that we're supposed to medically board people out.

And after the regulation changed, in my community, from the line, the calls were, "If you do this, you implement this reg, basically all the allergists and immunologists in the entire Army, probably the Navy and Air Force, will be conducting the medical boards full-time. And we have lots of generals, admirals, et

cetera, who have asthma and function in their jobs." That's the truth.

It is much more complex than that. Yes, the asthma screening requirements are simple, but to admit asthma, I think one of the challenges is: How do we make people as functional as possible and keep going and not exclude people who could potentially service with great diligence?

I think it's a motivational issue. Asthmatics who want to serve and are motivated and are quiet with their medication have a tremendously good track record.

And those numbers based on just throughout the databases, the reliability of the diagnosis is just not there. We're always in our work-ups changing the diagnosis.

MODERATOR FLETCHER: Thank you.

I believe Dr. Stevens was next.

DR. STEVENS: Just a simple question, I guess. The 72 percent that concealed their asthma, are these ones that there was a diagnosis or that an event took place?

CPT CLARK: How that 72 percent was obtained is when people go to basic training and, for some reason or another, either they're

diagnosed or they just reveal that they have asthma, they don't like it, they go in and try to get out, for whatever reason, they'll go into the health clinic or to see a health care provider.

And people that receive an existing prior-to-service discharge for a condition that existed prior to service that was diagnosed within the first six months of active duty, the paperwork that is filled out by the physician, the processing paperwork, that discharge paperwork, is sent back to the Military Entrance Processing Command in Illinois.

And they tally these up. Usually by reading the soap note or whatever the physician wrote, they'll determine: Was this the MEPS' error? Was this person waived? Was this person appropriately waived or did the person conceal their condition?

And in looking at a large quantity, hundreds of the EPTS paperwork, the hard copy forms, most often it will say in there in the subjective part of the health care provider's note, "Recruit concealed their condition. Recruit was hospitalized for asthma but did not tell MEPS physician." And then some of them will say they told their recruiter, and some of them

will say they did not tell their recruiter.

So that's how we get that 72 percent of all the EPTS paperwork that is returned to the Military Entrance Processing Command, which is only about 85 percent of it. It's not all. It doesn't all get back there, but out of the ones that were returned there.

MODERATOR FLETCHER: Dr. Sokas?

DR. SOKAS: Yes. I think that there is a tendency also among pediatricians to not diagnose asthma because of concerns about labeling, particularly in younger children. So you are going to have a certain number of people who, in retrospect, when you look through clearly have had asthma but had maybe not been labeled.

CPT CLARK: Right.

DR. SOKAS: I was wondering if the methylcholine challenge, while not specific, might be sensitive enough to identify people for whom some surveillance might be warranted that would prevent people from going inappropriately into situations where they might be under-medicated or not medicated at all.

MODERATOR FLETCHER: Dr. Engler?

COL ENGLER: Recently one of my staff wrote a review article with a pulmonary group

about the problems of bronchospasm and the fact that bronchospasm victims and their sensitivity, there are amazing problems.

If you exclude based on methylcholine challenge, the question has been asked: Can you afford to exclude that --

DR. SOKAS: The question isn't exclusion. It's identification and follow-up.

COL ENGLER: Well, there are a lot of people who have been fraught with a number of long-term epidemiologic data. Using the recent NIH guidelines on the asthma, there are people with positive pulmonary, people who have hay fever, who never go on to have asthma.

So the cost of doing that and the value of it, what we really need is an education on asthma for providers, level of primary care provider recognition and early intervention. We're still working on making sure people get inhaled steroids and trying to validate that.

DoD has put out that the NIH guidelines will be the standard and have us make sure people learn it considering they were put out four years ago and now again it's five years. It will be common practice. We're still treading on that level.

There is increasing data that early treatment intervention may prevent chronic asthma, certainly irreversible lung disease. So it's, unfortunately, not a simple test that's going to really work. We're still working on it.

I just want to make a comment about the recruiters tell the patients to lie. And that's the truth because you have these young strapping guys who can run ten miles, who do everything, who could be Olympic athletes, and they had asthma at one point and they probably do have underlying asthma.

And the recruiter looks, "I've got prime meat here. I've got to meet my quota. It's difficult. It doesn't make sense to exclude this person." And they get mixed messages as well. So there are a number of institutional dishonesties that contribute to the situation. It's very hard.

CPT CLARK: I just wanted to make one more comment. I think it would be presumptuous of me to ask the Board a question right now since I'm not in a position to act on the recommendations of the Board. So this is mostly an information briefing, but I just wanted to sort of lay out some of the issues that are being

discussed in the working group.

One is looking at the directive. Is it right? Should we be excluding everybody that has had asthma reliably diagnosed at any age? And does that need to be more specific, keeping in mind that the more specific you get, the higher probability of people interpreting it other than in ways in which you wish them to increases?

People are also discussing whether there should be some sort of screening test done on all recruit applicants at the MEPS to try to pick up the people whose recruiters told them to lie that have asthma that's bad enough that it's going to inhibit them in basic training and then fulfilling their obligation.

And people have training and doctor in command has come up, also been discussing: Should we be doing spirometry on everybody at the MEPS, issues like that?

And then the other issue is: Should the waiver guidelines change? Should they be directed to look at other things, like mental aptitude scores, or should they not be waiving anybody? Those are just some of the issues that are being discussed.

MODERATOR FLETCHER: Dr. Sokas?

DR. SOKAS: It does seem sort of clear that it hinges on the waiver process and who is informed of the waiver because if the recruiter were to say to somebody, "Okay. You've had asthma. You need to be honest about it," but then here's the waiver process and it's pretty automatic and straightforward as long as it wasn't a terrible, debilitating disease, then that's one thing.

But if you have a waiver process that only the sophisticated manage to figure out about, then you've got a really unfair and dysfunctional system. And it may hinge on that.

CPT CLARK: And the waiver process is different in each of the Services also. There are Service-specific waiver authorities. And they have different criteria for waiving people. They also call things waived differently.

In the Army and Navy, if they see someone, they, for some reason, determine that it's not really truly asthma or if it's not truly asthma, they get waived. If it is truly asthma but they think they're going to do okay, they get waived.

And there's a distinction made in the

Air Force if the person comes down, the Air Force waiver authority gathers more information and determines that the person really doesn't have asthma, they are not given a waiver. And they are not considered waived in their database. They're just considered shouldn't have been disqualified.

So when you look at Air Force waived people, there are fewer people because those are only the people that the waiver authority has determined they do have asthma, but they have been waived anyway.

MODERATOR FLETCHER: Other questions, comments? Please identify.

COL GARDNER: Dr. Gardner at USUHS.

Nonsensical rules promote dishonesty. It's data like this that helps us to make rules more sensible. The one problem here, though, is that the waiver tends to favor those with mild conditions; whereas, those who slip through may have more severe conditions.

Do you have any kind of feel for what the mildness level of asthma is that gets waived and how to distinguish between those who have moderate or severe asthma comparing those who don't?

CPT CLARK: I don't have a good feel for that because, like I said, the availability of information on the severity of asthma is lacking in almost every data source that we look at, including hard copy paperwork from the waiver authorities and the MEPS physicians.

MODERATOR FLETCHER: Other questions, comments?

EXECUTIVE SECRETARY FOGELMAN: There will be more opportunity to discuss this in the Health Maintenance and Occupational Health Subcommittees today and tomorrow.

We're not necessarily asking for a written recommendation from the Board at this time. In fact, we're not. But any feedback you want to give with regard to this issue, it would be helpful.

CPT CLARK: Thank you.

EXECUTIVE SECRETARY FOGELMAN: Thank you very much.

(Applause.)

MODERATOR FLETCHER: Puts us in a rare state of affairs: ahead of time. We're going to make an administrative decision and move on to another topic after the break and add that topic back. If anyone has to break --

EXECUTIVE SECRETARY FOGELMAN: Is there anyone who absolutely has to break at this time? We'll watch you as you walk out.

We're going to change the schedule slightly and go on to a Southwest Asia deployment update, Major Don Thompson, who is the preventive medicine consultant for the Epidemiological Services Branch from the Air Force. Major Thompson?

SOUTHWEST ASIA DEPLOYMENT UPDATE

LTC THOMPSON: Good morning. I'd like the record to reflect that I had more than a two weeks' warning to prepare this briefing. I am going to briefly talk about why the -- well, an overview of deployment surveillance, the issues behind what was going on about a year ago.

I took the first Air Force theatre epidemiology team to Southwest Asia. So I'm going to describe why we went, what we found, what we did while we were there, where we are now, and where we hope to go.

I was expecting to follow Colonel Rubertone's talk about the defense medical surveillance system. So I referred to him a little bit in here. But I guess we'll just get more information from that once he presents his

briefing.

Next slide, please. The challenges here in Southwest Asia were we're dealing with three Services, so many different processes, many different case definitions.

We had 15 sites that were spread all over the Arabian peninsula. Some people lived in tents. I lived in a tent in the desert for a while. Many people did. Other people lived in four-star hotels in capital cities. We had very differing communication support.

Some places you could pick up a telephone and use your AT&T card and get back to the U.S. Other places you could go for a week without even being able to get any kind of e-mail out.

Because of the different sites, different priorities, different missions, the deployment lengths were varied. We had people who were in country for only 45 days. We had people who were PCSed who had a permanent transfer to the region for two years.

So there was a very different perception of risk among the Service members, the individual Service members, and their line commanders. Some people thought that, "Yes, this

is really a dangerous place to be. I can't wait until I'm out of here."

And then there were other people as they walked from their air-conditioned house to their air-conditioned car and drove to their air-conditioned office in street clothes and were able to go to a brick commissary at lunchtime, things just didn't seem to have the same degree of urgency to those of us who were living behind barbed wire on the desert.

There was about a three percent personnel turnover each week. We didn't have large units, hundreds of people who were in-processing, would stay for 90 days or 180 days and then leave in general. Occasionally that happened, but, by and large, we'd have maybe 10 people out of a shop of 100 who were leaving every week.

So there were constantly new people coming, old people going. And because of that, the in-processing and out-processing system had to have a very low mission impact. We couldn't just shut things down for 48 hours while we in-processed people or out-processed people.

For example, the security forces, when they came into the theatre, they were required to

be on post armed and functional within 36 hours of their walking off the plane.

Some of the security force squadrons were minimally manned to the point where they had to go to extra shifts. They had to extend their 12-hour days to 16-hour days just to support these turnovers.

So there wasn't a lot of welcoming with open arms of our suggestions to do some different kinds of in-processing and out-processing health surveillance.

Okay. Next slide. What we found when we got there was data collection on disease. Non-battle injuries was at the aggregate level. Basically people were using a stubby pencil and hash marks on a piece of paper. They were actually doing it electronically, but they put it in an Excel spreadsheet and print out the log at the end of the day and put the piece of paper in the log book.

Some reporting was being forwarded to higher headquarters, but most was not. The case definitions, as I mentioned before, varied, sometimes dramatically.

There was no look-back capability. If you had suspicions that there had been some kind

of a problem a week or a month or a year ago, there was really no ability to go back and look at that, either at the individual level or at a subgroup level. And because of that, this collection system was of minimal value for epidemiologic investigations.

Next slide. These next few slides have some examples of how when we went and started putting this DNBI data into some kind of a presentation format, this is how we presented it.

This goes from when the bed-down at Prince Sultan Air Base -- this is the base out in the middle of the desert that the folks moved from Dhakran after the Kobar Towers bombing. They moved to Prince Sultan Air Base in the middle of August 1996. This is the first six months or so.

The denominator is gradually increasing over this time. The size of the base increased and stabilized in the 3,500 to 4,500 range. But then more Air Force sites gradually came online and began reporting.

So the denominator is steadily increasing, but you can see the rates for in this case respiratory infections and diarrheal

infections were as indicated.

We were collecting data using the 17 DNBI categories from the Joint Chiefs of Staff that had been set of less back in 1994-95. This is just two of those. This is the two that had the most communicable disease risk.

This slide actually has all 17 categories on it. So if you're looking at it on your own computer, you can look at rates for all 17 categories and can present them on the graph. Of course, this looks too busy if we put them all there.

Communicable disease rate on this slide. You can see we had a nice bump in respiratory infections in December. Four of those were actually confirmed to be the influenza A, I believe.

Injury rates we recorded by: sports injuries, non-sports injuries. And then motor vehicle accidents were almost nonexistent. So I took the line off the graph. And you can see that there's obviously an increase in injuries when people are out there building tents and smacking their thumbs with hammers.

Appropriately, the sports injury rate started to rise gradually as the base stabilized

and people realized that they did have a life, they were going to be there for a while. So they started taking out their aggressions on each other.

Next slide. And then a summary slide of overall injury, overall disease, and then total rates. This doesn't answer a lot of questions, but it's reassuring to the folks on this side of the Atlantic that people are looking, people are watching. And if something bad happens, there's somebody who will probably take action based on that.

Next slide. Now, what we needed to do a better job, though, was a system that was simple and portable that would provide individual-level data. It would provide the capability of looking back. And it would have some kind of action thresholds.

A number of the sites in the desert, quite a few of them, had more than one physician. There were three or four sites that had just a flight surgeon taking care of the aircraft that were there. And there were several sites that had an independent-duty medical technician, a medical person, who had a few months of additional training but was by no means a

preventive medicine officer.

So we wanted to be able to establish some action thresholds in this electronic system that would raise some red flags if there were something more that these people needed to be looking at.

Next slide. So what we did in response to those needs was to develop an electronic medical encounter system. This automates collection and reporting.

Some of this is done. Some of this is still in process. The system exists. It's collecting the demographics, chief complaint, when the person started to have their symptoms, where they were billeted.

If someone checks a respiratory complaint or a gastrointestinal complaint, then a form comes up and asks them eight to ten additional questions that we would like to know if we're investigating some kind of infectious process.

And then the provider would put in a diagnosis that's linked to an ICD-9 code and a disposition, whether this person was returned to duty, was admitted to the hospital, put on quarters. And then the system has the ability

for electronic transmission to us at Brooks Air Force Base so that we can look at the aggregate of these individuals and have some oversight and then put this in the appropriate format for presenting to higher headquarters.

Next slide. What we did in Phase I was a system, a program that's based on Microsoft Access. It started. It was initially deployed in actually December. And it was pretty much throughout the Air Force sites in the desert, which is, I believe, 10 of the 15 sites.

It was deployed to all of those in the springtime, in March of '97. And the data file is either e-mailed or FTPed into Prince Sultan Air Base and then forwarded on to the U.S.

This is being taken to an advanced phase that will be Web-based. This will allow daily reporting. It will allow daily look-backs, rather than weekly, as we have in Phase I. And then the database structure is compatible with the defense medical surveillance system, which you haven't heard about yet this morning.

This Phase II version was modified a few months ago. The system that was under development required communication support that just still does not exist in the desert.

The communications there are still based on a tactical environment where you don't always have wires that work. You don't always have satellite dishes that are up. And so this Phase II has been toned back somewhat so that it doesn't require the kind of communications that are readily available here in the States.

Next slide. So where we are today, we have 65 percent of the theatre on this Phase I access-based program, where we're capturing individual-level medical encounter data.

We have real-time reporting available. We're not counting on it yet. We're still using the old weekly system. But the real-time reporting is available. It's based on ICD-9 codes. Data elements can be archived into the defense-level system. And we're working on establishing some electronic action thresholds.

We're still struggling with implementing the system across all the Services. Again, we have a fixed military medical treatment facility that is doing business just fine the way it has been for the last five years. And this is a new system that doesn't offer this fixed facility the same that it offers folks out in tents out in the desert.

And, then again, the case definitions and different priorities of the different Services is still an issue. So we're still reporting based on the DNBI categories, but we can go a little bit farther than that.

Next slide. This is an added summary that has come online in the last few months because of the interest in the environmental issues, where it summarizes samples from different media taken at the different sites.

And then there's a little green, yellow, or red traffic light there on each one. If thresholds are exceeded or there is a potential danger site, then that green light somehow changes to yellow and then to red to indicate that action is being taken.

Last slide. The remaining issues that I have not an easy answer to, pre and post-deployment, mental health surveillance. Discussions are continuing on a daily basis what should be done in that area, compliance with such a surveillance system. We want to simplify the process as much as possible to increase compliance, but if we simplify it too much, we don't get data that's useful to drive interventions.

The pre-exposure risk assessment is really what drives what resources should be there, what degree of surveillance should be there. That has yet to be institutionalized.

We're still relatively used to dusting off plans that are on the shelf that have been developed over the last year or five years or ten years. And we're realizing with today's environment changing as much as it does, we need to be more dynamic and perhaps doing a pre-exposure risk assessment each time we're doing -- well, a more in-depth pre-exposure risk assessment each time we're doing a major or a minor troop movement. And the different Service processes and support levels is certainly an unresolved issue.

Any questions?

MODERATOR FLETCHER: Thank you, Major Thompson.

All your questions? Please identify yourself. Dr. Perrotta?

DR. PERROTTA: Good news on collecting more complete and certainly more timely information. I hope it continues to grow. You're getting good information on the numerators. How do you collect in a similar

fashion, if you do, information on the number of people who are there?

If your medical staff are out filling out these forms and e-mailing this stuff to you or filling out the computer forms, e-mailing that, that's useful for determining if there is something going on which we need to do some rates, how do you collect that denominator information?

LTC THOMPSON: We're getting weekly troop strengths from each of the sites. That raised some eyebrows initially because of security risks from ten years ago, but we're realizing that these troop strengths are sent separately sometimes to pull them out from the numerator data. But those weekly troop strengths are now coming.

DR. PERROTTA: That's reasonable. Thank you.

MODERATOR FLETCHER: Dr. Allen?

DR. ALLEN: Can you describe a little bit more the development of the surveillance thresholds at which there is an alert or action should be taken and how specific those are for each condition?

LTC THOMPSON: Today they're not very

specific because the DNBI categories are still relatively general. We're taking this individual level system to the point where we're actually going to pull out the ICD-9 codes.

Right now our DNBI category for respiratory infections includes sinusitis. It includes a number of respiratory conditions that are not classically or are not at high risk for being communicable from person to person.

So we are pulling out the specific ICD-9 codes. And then we're going to look at our historical data with those ICD-9 codes and try to establish a level that seems to make sense that will say, "Okay. Here is a problem. We need to take action or there isn't one."

But given the current state of the generality of all of the different things that are lumped into a DNBI category, the thresholds today aren't real sensitive.

DR. ALLEN: Is it strictly a numerator-based threshold system or, as Dr. Perrotta was I think implying, is it a rate-based system?

LTC THOMPSON: It will be a rate-based system, but, therefore, it will vary according to the site. We have a site with 150 people. We

have a number of people who will come in and complain of diarrhea, for instance. And we may bust the rate if three people get off the airplane and then come in complaining of diarrhea. And that's happened frequently because of the small denominator.

So these thresholds will apply to the larger units, the bases, the sites that have larger groups of people. But they're going to have to vary somewhat depending on the Service. For instance, the Army is a little bit more physical than the Air Force. And there are sports injuries and occupational injuries.

Well, what do you call an injury that you get during physical training? Is that a sports injury, an occupational injury, or an other kind of injury?

So that has to be worked out. We can't use the same thresholds for those because the case definitions vary somewhat.

MODERATOR FLETCHER: Dr. Chin?

DR. CHIN: My question is somewhat related to that in terms of the size, the analysis in terms of calculating rates. Are you going to be routinely looking at units, companies? What's the basic sort of unit that

you're going to be looking at?

LTC THOMPSON: Well, the unit now is determined by physical location. We have one site that has about 4,000 people. We have 3 or 4 sites that have 1,000 to 1,500 people. And then we have a lot of small units that may only have 2 to 3 hundred people.

In a few of these sites, we have more than one Service. We have Army and Air Force people that have sometimes collocated but different reporting. Well, there will be an Army and an Air Force medical treatment facility in the same tent almost, in the same group of villas in one area. And they use a different reporting process, and they use a different case definition.

So that's one of the major challenges, determining what works for Southwest Asia when we're looking at two Services, two different kinds of case definitions, two different processes for reporting. That's why it's unsolved.

MODERATOR FLETCHER: Other questions? Dr. Baker?

PROFESSOR BAKER: Is your troop strength information just the total number of

personnel in an area or is it subdivided in terms of Service and gender and rank or anything else?

LTC THOMPSON: All we're getting now is number of people assigned to that unit by week. So we don't have it broken down farther. That's available, but we haven't asked for it.

PROFESSOR BAKER: And your information in terms of injuries, as far as cause of injury, are you using stannic codes or what types of codes, e-codes? What do you use for the circumstances of injury?

LTC THOMPSON: The Air Force sites that have this access-based system are using ICD-9 codes. And then they have the appropriate modifiers that will take that to the next degree of sensitivity.

MODERATOR FLETCHER: Question? Yes? Please identify.

COL DINIEGA: Colonel Diniega.

I noted with interest the data that was presented on the environmental and occupational samplings, realizing that those are probably just the number of samples taken from different elements.

Water is a routine sampling methodology in the Services. We're required to

do that. But the air and soil samples, what's driving those samples?

LTC THOMPSON: Major Kim?

MAJ KIM: I'm going to give a talk in the environmental working group on that. There is presently a joint environmental surveillance group looking at this exact issue.

What was done in the case of Prince Sultan Air Base, for example, and kind of Major Thompson was talking about. We're hoping to be able to eventually create a database using GIS and other techniques where we can do an up-front risk assessment, hope to make some smart decisions about where we're placing troops and where we're placing various portions of various operations and hopefully avoid a Gulf War illness-type situation, have the data up front, as well as be able to do a retrospective in the event of our medical outcomes so we will have at least some environmental exposure data to move in and move out.

COL DINIEGA: I understand that, but what I'm asking is: Soil sampling is not routinely done. So somebody is asking for the soil samples based on a presumed risk export. That's what I'm saying. Do you know what the

reason for the soil sampling is being shown on here?

LTC THOMPSON: Phil, there were some sites where there were rumors of problems. When we went, there was a squadron that had been assigned to a base in Bahrain. When they first got there, there were four or five or six sea turtle carcasses on the beach. So people were sure that the water was contaminated because of that. So there was additional water sampling done there.

There is an industrial plant within sight of another location with a plume that was obvious most of the time. So there was a perceived risk of air pollution. So more air sampling was done. Those perceptions drove some of the increased sampling.

MODERATOR FLETCHER: Other questions, comments? Dr. Perrotta, do you have another comment? You've made a big contribution to this area.

DR. PERROTTA: No. I'll be interested in hearing a little bit more in the Environmental Health Subcommittee and hopefully encouraging the AFEB's input into the process that we're talking about.

EXECUTIVE SECRETARY FOGELMAN: And there will be further discussion in this area this afternoon, both the environmental piece and overall.

Thank you.

MODERATOR FLETCHER: Thank you very much.

(Applause.)

EXECUTIVE SECRETARY FOGELMAN: Okay. It's 9:20. We're scheduled for a break. So why don't we take a break and plan to be back at 9:35?

(Whereupon, the foregoing matter went off the record at 0921 a.m. and went back on the record at 0943 a.m.)

EXECUTIVE SECRETARY FOGELMAN: I have a couple of announcements while we're waiting for the Board members. If you would also please add Dr. Poland's name to your list of potential nominees? Sorry about that.

And if you absolutely do not want to be nominated, would you please raise your hand now? Okay. Hang on. All right. I'll announce it as soon as I get it. Anyone who absolutely does not want to be nominated?

(Whereupon, there was a show of

hands.)

EXECUTIVE DIRECTOR FOGELMAN: Okay. The names I have for you to cross out are: Professor Baker, Dr. Jackson, Dr. Sokas, Dr. Waldman, and Dr. Weinstein. Everyone else is good to go. We've added Dr. Perrotta and Dr. Poland to the list.

Now, we will probably or we'll at least discuss selecting also a vice person. We can talk more at lunch about this.

MODERATOR FLETCHER: This is mainly for a president-elect who would take over in July.

EXECUTIVE DIRECTOR FOGELMAN: Right.

MODERATOR FLETCHER: I'd like to thank everyone for keeping the discussions on time this morning. That was certainly a record today. It certainly makes a smooth early morning. So we will begin the second session.

Colonel Fogelman?

EXECUTIVE DIRECTOR FOGELMAN: We have with us today Dr. Mark Rubertone, who is the chief of the Army medical surveillance activity. He will be talking to us about the defense medical surveillance system. Some of you had asked for this briefing to be held at this

meeting, and he'll be doing it for us.

Mark?

DEFENSE MEDICAL SURVEILLANCE SYSTEM

LTC RUBERTONE: I'm going to be sitting down during my briefing so I can access the keyboard here. So if anyone can't hear me --

MODERATOR FLETCHER: Just speak loudly, Mark, so everyone can hear.

LTC RUBERTONE: Okay. I will try. I notice some familiar faces around the room. So I hope that my jokes don't seem too stale to you all. I'll try to use new ones.

What I'm going to do today is show the defense medical surveillance system. I'll first start off with a functional overview, what we call medical surveillance decision support and kind of how we define that and what goes into that concept. And then I'll demonstrate the defense medical surveillance system.

Another system that I'm going to show is the defense medical epidemiology database. I think the feedback I've gotten from this presentation is that people often meet with a little bit of confusion about the DMSS and the DMED. I hope to clear that up, and I'll start right now by saying the system, the defense medical surveillance system, is, in fact, where all of the data is integrated and all of the data

lives on for the most part active-duty Service members with some other data in there.

The DMED is a remote access solution for the DMSS or the DoD surveillance. In fact, I'll give everyone who wishes the home page address, where you can download the DMED software and have exactly what I am going to be doing here over an internet connection, that kind of access to the data without identifying information about any kind of Privacy Act data.

So that's a distinction between the DMSS and the DMED. And, as I said, I'll give a demonstration. I'll have to sit down for the majority of the demonstration. And you'll see why when I do that. I'll try to talk loudly.

This is the organization of AMSA, the Army medical surveillance activity. It's underneath the CHPPM in the Directorate of the Epidemiology and Disease Surveillance.

The areas that we focus on at AMSA are the operation of the defense medical surveillance system, also the defense medical epidemiology database, which I mentioned. And we also manage and run the DoD serum repository. I'll talk more about all of these things in a little bit.

This is my concept of comprehensive

military medical surveillance and the strategy, the migration strategy, that we have been undergoing for the last four or five years.

We fall under the MHSS business area, the executive information systems and decision support. If you all are not familiar with that, the MHS -- actually, it's been renamed the MHS -- is the military health systems that provide all of the automation support for the medical care of DoD.

We started out as an Army medical surveillance system back in 1992 and have now transitioned to a defense medical surveillance system. And that's what I'll be showing right now.

I think we're on a path to comprehensive military medical surveillance. And I think really the only way to accomplish that is to have a DoD medical surveillance agency. It's just an Army medical surveillance agency. I can say that the other Services have assigned individuals that will be assigned to work at AMSA on the DMSS functional requirements. I think that's the first step in really having a DoD medical surveillance agency.

I won't read the definition of medical

surveillance, but I will highlight three very important elements of it that we try to keep in mind when we state the objectives of this system. And that is namely that the data be collected routinely and systematically, that we have a capacity to analyze, interpret, and report that data regularly, and that it's a population-based data.

The last concept is one that sometimes gets missed in my feeling on what are called surveillance systems because it's either a nonspecific population or it's just not the same type of surveillance that we can do on the active-duty military.

And what I mean by "population-based data" is that we start from pre-induction, post-discharge capturing all data that is relevant to an active-duty Service member's or reservist's, Service member's, military career. And by that, we start with right in the MEPS station, the military entrance processing station, getting whatever data is already automated at that site.

We're very dependent on outside systems and databases that feed into our decision support system. We get the HIV tests at that

time. We get their assignments, deployments that they're on, any inpatient hospitalizations for the active duty. Reportable diseases right now is just for the Army, but we had a meeting yesterday to incorporate the Navy's and Air Force's reportable disease data into the DMSS.

We have just started receiving ambulatory data, which is a very incomplete system, the ADS, in the military, but it is I envision the way that we'll get access to all ambulatory data in a few years from now.

We have health risk assessments, which is a self-assessment tool that's used by the Army to look at smoking history, suicidal ideation, depression, stress, those kinds of things. This will be replaced by the HEAR, which is the DoD system that the Air Force has the lead on, which will basically be the same type of assessment and evaluation data.

We manage the DoD serum repository. And in there, we have all the HIV tests that are done on the active and reserve components for all three Services. But also we are now beginning to have mostly post-deployment specimens drawn specifically for the purpose of deployment, but also it's been used for pre-deployment and

post-deployment specimens.

This dotted line, environmental exposures, is on there because we don't have that data. And I don't think that data is in a standardized, population-based format right now that we could link into. But there's a lot of talk and a lot of interest in having environmental exposure data become part of the DMSS.

This is a projected data integration slide. Most of the stuff in the bubbles we actually have online right now, but some of it is projected because it's what the information management community for the DoD is projecting as what they would like to have.

For example, the health data record, which is going to be a computerized patient record, doesn't exist today. It's projected. But the inpatient and the ambulatory data do exist. And we get that data. We just don't get it through the health data record. It's hard to see this slide, but there are arrows up there.

The other thing is the reportable diseases. We have in-theatre. Inpatient data we have. The ambulatory data we don't have from the theatre. From the Defense Manpower Data Center

is where we get all of our personnel data and all the deployment rosters.

As I said, as immunizations come online, immunization tracking system, or environmental exposures, we'll add that data into the defense medical surveillance system.

One of the things we do at AMSA is not just sit on this data, but we actually look at it. We run a number of requests, approximately 200 to 225 requests, a year. And we publish our analysis of some of them or ones that are of interest for other reasons, military reasons, in the medical surveillance monthly report that comes out monthly.

At one time, all of the members on the AFEB were on the mailing list for this, but I think there's been a high enough turnover that it's probably a good time to get the updated list.

We have published on this cover our home page address, which is AMSA@ARMY.MIL. And you can actually download and print out all of the MSMR reports going back to our first issue three years ago.

This is also the Web site address that you can download the DMED software. Anyone --

EXECUTIVE DIRECTOR FOGELMAN: Can you read that off?

LTC RUBERTONE: Yes. It's AMSA. -- that's AMSA -- ARMY.MIL. And you don't need WWW or HTTP. Just put that into your browser if you have an internet browser, and that will get you to our location.

We routinely for the Army every month publish sentinel reportable diseases as well as track the two-year trend of those diseases. And that's just what this page is. You can see all of this data, as I said, online or in hard-copy form, which I actually don't have any hard copies with me right now.

This is a specific example of what we did during Bosnia deployment. We looked at hospitalization rates and published them every month looking at injuries, diseases, and battle casualties during the Bosnia deployment as well as just this table broken down by ICD-9 categories.

Okay. I'm going to move on to the demonstration of the DMSS. And that's really for the most part why I need to be seated.

COL DINIEGA: Mark?

LTC RUBERTONE: Yes?

COL DINIEGA: As you're working the computer and we're waiting?

LTC RUBERTONE: Yes?

COL DINIEGA: Why is the oldest database not included as one of the --

LTC RUBERTONE: That's a good question, Colonel Diniega. OHMS, which is now DOHRS, defense occupational health system, -- I'm not sure what the "R" stands for -- mostly exists such as CHCS may exist in the hospital to help manage the occupational health clinics at a local level. There hasn't been a concerted effort to get that data into a centralized database that we can now tap into at one location. And the analogy for CHCS would be that that data becomes the DoD standard inpatient record SIDR. So we can easily tap into one location for the SIDR and make it part of the database.

If the DOHRS data, or the OHMS data, ever did become available in that format, we would love to have it as part of this system.

This is the defense medical surveillance system. And this is what we use at the Army medical surveillance activity to get access to the data and to be able to look at the data. This is not the DMED. And when I show

that later, that's what provides remote access.

I'm going to start with the data dictionary. That's the easiest place to just show the types of data and the magnitude of data that we have in the system. This is just a limited set of our database, but it's major ones.

I'm going to start with person. We have now in our database over six million individuals that represent the active duty, reserve, and National Guard. These are unique individuals. And these are the actual fields that we collect on these individuals.

Just in order to be able to quickly look at the data and make sense of it, we have certain fields because it's appropriate to do so where we can explode out for sex, for example.

We can look at the gender of the six million people and see that's the breakdown: 87 percent male, 13 percent female, and the actual numbers. And some people are undecided. The same thing with race.

It wouldn't, of course, make sense to do data first because you'd just get the 365 days of the year. But where things do make sense, we try to have them explodable, which is kind of a precalculated online way to look at the data.

For six million people, it becomes a challenge to manage. But when you get to the demographic data, we have over 40 million different rows of demographic data on these individuals, 43 million. That includes the active-duty and reserve components.

It doesn't make sense sometimes to explode these, but let me go to the active duty, where we have 34 million. And I can look at service. This is just for the current active duty. This is the break down for the current active duty, who's in the Army, Coast Guard, et cetera, Air Force, Marines, Navy.

Even though there are 34 million rows of data, I may have 10 or 15 rows because every time I've changed assignments or have changed my MOS or been promoted or whatever has occurred, we keep track of that in longitudinal fashion.

This person, DEMOG, these tables, form the real heart of our system. It's also the population that we conduct surveillance on. Everything else links to these tables in some form or another.

The other databases that I'll highlight here, the SIDR is the standard inpatient data record. And that has 1.6 million

active-duty admissions going back to January 1990.

And, again, we have a number of fields more to meet our needs to quickly look at the data. So if we want to know how many autopsies were done in that group, we can see 597 autopsies were done on those particular admissions that resulted in death.

We have the SADR online, which is new. Just in the last couple of months, we were able to add ambulatory data. We have eight million records that represent visits to medical treatment facilities, either clinics or battalion aid stations, MTFs, et cetera. This is not completely deployed in the DoD. So I don't consider it complete data, but it is a first start at getting ambulatory data.

Our reportable disease data, which is right now just an Army-only system, is 31,000 reportable diseases that have been sent to us over the last 3 years in an automated fashion.

We keep track of all the deployments since the Persian Gulf War. So, actually, we do have the 696,000 people that were deployed to the Gulf as well as another 145,000 individuals that were deployed to various other operations.

I can explode out this operations field to see that 101,000 of those individuals were somehow related to the Bosnia deployment, 25,000 to Haiti, 6,000 to Kuwait. These numbers, as anyone in uniform may know, do not represent how many people may have gone to Somalia or Rwanda.

There was no system to collect that data in the military back then. We've had to in some cases retrospectively get that data or do what we can with what they've provided. So it's not very complete. I would say Bosnia is the only real complete database we have on deployments.

As all of the individuals that have processed through the MEPS stations, a lot of these individuals end up on active duty. So there's duplication between MEPS and person, but we keep it for its own purpose because it allows us to look at geographic variation as a risk factor for various conditions, et cetera, as well as some individuals who don't go on to active duty for various reasons. It's a good snapshot of the country as a whole. So we keep the MEPS data and all of these types of databases on those individuals.

The health risk assessment, as I mentioned, I think we have about 600,000, 692,000, health risk assessments performed on the Army. All in all, we have over 120 million rows of data that we have amassed in this system to be online in an integrated, rapidly accessible system for answering questions, doing queries, and the like. And now I'm going to show you some of that data.

First, I will do what we call a data look-up. I'm just going to use my Social Security number, although anyone who has been on active duty or the reserve component since -- well, for the Army, this goes back to 1985; for the other Services, it goes back to January 1990 -- would be in this database.

Right now I'll just ask for my person, my demographic information. I could also ask to see hospitalizations, that ambulatory visits, any deployments, any reportable diseases as well.

What just happened in the blink of an eye was I queried the table that had six million rows to return this one row that sort of says that I'm a white male, ethnic group, et cetera, et cetera.

But I also queried the table with 43

million rows to get these 15 records that show my assignments and changes in demographic information over time.

So the last one, which I think is up to September of '97, finally shows that I was promoted, thank goodness, and that I remained in the medical corps, et cetera.

What this allows us to do is to do longitudinal studies; for example, looking at person-time related to a particular military occupational specialty, rather than just individuals.

So we were at one time asked to look at the effect of fuel handling in women and the outcome of abortion. We were able to look back in time to get the exact details of that study. We could calculate person-time for female fuel handlers and then compare to a control group that was not in that MOS looking at -- I'm sorry. It wasn't abortion. I believe it was ectopic pregnancy that we did. But we could look at the outcomes and the results from that.

I'm going to move on from this data look-up unless anyone on active duty wants me to look up their record. I'm going to go to something we have, which is our deployment. This

is really more a show and tell-type thing than an actual something we use for analysis. It allows me to demonstrate the capability of the system quickly, but, as you'll see, there are limitations in what data you can actually get back.

This simply just allows us to choose one of the operations, the Persian Gulf War being too large to put on here for demonstration purposes. So it doesn't make it. But I can choose Somalia or any of the other ones. And then I can choose any category or subcategory of ICD-9 code, but I'll just choose infectious and parasitic diseases.

Then what we have done is we have taken the 8,700 people or so that we have deployed to Somalia, and we prematch them to controls that did not deploy based on age, sex, length of time in service, things of that nature.

So when I hit this graph, this will be looking at hospitalized cases for the one year prior to and the one year post, the date of the case involved in this instance to a matched control.

And you can see, as you might expect, that infectious and parasitic diseases do go up

during deployments. You can click on this bar to actually look at the records that it contains. So you'll see some malaria, vivax malaria, shigella, and the like. That occurred in the year during and following the deployment to Somalia.

Again, this is just yet a very quick rough estimate of what's out there, as opposed to doing the full-blown study, which you wouldn't be able to do. And here you wouldn't be able to control for all the factors of interest.

Another thing that we keep track of in the defense medical surveillance system is requests that we do for various people and organizations over time. I'll just pull all of the requests up.

I think there are 325 different requests that we have done for DESPR, various things. Let me go down here and cheat a little bit and go to one that I think might be of interest to this group.

Major Fisher asked us to look at vaccine-preventable diseases in active duty. So we did. And Kohlhase just happened to be -- Kimmie Kohlhase is our analyst that did this. If I click on this, it opens up just a little bit of

a log telling us when we were asked to do it, what we were asked to do, et cetera.

We keep our own project log as to what we needed to do in order to run this so we can re-create it. We keep all of the files that are related to this particular request online. And we even keep a query so if we need to rerun this query, et cetera, we can do so.

I won't run this query because it's a little bit too complicated or would take too long for a demonstration, but there are other queries that I can run.

EXECUTIVE SECRETARY FOGELMAN: You'll see the results of that query.

LTC RUBERTONE: You'll see the results of that query. That's correct.

Back in January or so, we looked at cold weather injuries amongst active-duty Army individuals. And we looked at a two-year period, January of '95 to December of '96. We wanted to know of all cold weather injuries that were reported to our system.

So I'm going to go to the query here that we've saved and actually just run that again online. This will come up with all cold weather injuries in the Army for that two-year period of

time on active-duty individuals, comes back pretty quickly. We've got frostbite and unspecified immersion type, et cetera.

PARTICIPANT: Excuse me. Are you online now?

LTC RUBERTONE: I am. I should have explained that at the beginning. The reason I can give this demonstration here in this room is that we're on the Walter Reed campus, and we're on the WRAIR LAN. So I have an internet connection that's taped to the floor going back to the servers that we have of all of the data.

The system is run in Oracle on a UNIX system at the Army Medical Surveillance Activity. It's a rather large computer operation at this time.

This first part of this query to look at cold weather injuries was useful in and of itself, but what we decided to do is look at home of record as it may influence cold weather injuries. So I'm going to load another query that we've saved related to this request. And it just happens to be the number and home of record here.

This will take those people that we just looked at before and, where possible and

where available, we'll look at their home of record from the MEPS data that we have also online. And I'll run that.

This is really not a trivial request because it does have to first find the cold weather injuries and then look through the five million or so MEPS records to find out their home of record, but, as you can see with the new technology and relational databases, it does come back pretty quickly.

The other thing we can see is that we need to teach the people who grew up in the South how to dress a little warmer because they're really the ones that are at risk for cold weather injuries. Actually, Alabama and Georgia were the only two statistically significant states. And we published this last January in our medical surveillance report.

Okay. I'm going to switch gears now and describe just quickly the defense medical epidemiology database. Originally, starting back in September of '95, this was a program that was resourced under the Defense Women's Health Research Program.

They looked through the Services for those organizations that had access to

epidemiologic data. And what they desired was an epidemiologic-capable database that they could do studies on active-duty women.

Essentially the group that got together from the three Services envisioned a broader type of system. I think what they actually had in mind was the defense medical surveillance system. But that was a couple of years shy of that being a reality.

So we decided to come up with a concept to integrate the Army, Air Force, and Navy epidemiologic capabilities in an online way. Most of our time was spent defining standard methodology and standard data elements across the Services. And that took some interesting meetings and discussion to get that ironed out.

Our Phase I prototype, we were only able to include longitudinal personnel data and active-duty hospitalizations. The reason for that is there was no other database that we had available across the Services to include.

We didn't have reportable diseases or ambulatory data or anything else. We would love to have included that. And that's the next phase and step up an epidemic project, is to continually add things that are otherwise in the

defense medical surveillance system to this remote access.

The big plus of this particular system is internet access to either reports or actually to the data. That's what I'm going to show right now, a demonstration of this DMED application.

This is an application that, again, requires an internet connection. It starts off with an ICD-9 tree and the default looking for hospitalization rates.

There are other things you can select. You can look at first hospitalization rates, private incidents but not quite an incident, and the top ten diagnoses in the population, or you just may want to look at population numbers. For now, I'll just start with the hospitalization rates.

This is a little bit more of a user-friendly explorer or drop-down tree. First of all, it's all preloaded. So you don't have to do any waiting to get to the different conditions.

The other thing is that you can select, just as you would in I guess Windows-compatible programs, different diseases that aren't in the same category. I'll just do

this. I can't do it with the microphone, though.

So if that made sense to do, which it probably doesn't, we could look at these various different categories of diseases, as many as you want and ranges of disease, or you can just highlight a whole section and look at an entire section of disease.

What I'm going to do is focus on one, again, that I think the subcommittee this afternoon on vaccine-preventable diseases may be interested in. And I also think I just lopped it up. Oh, I didn't, just a little bit of delay. I lost the microphone. Well, well, well. Is this back? Okay. I'll try not to move.

Here we have viral diseases accompanied by example. I'll just use chicken pox as one of the new vaccine-preventable diseases. Next we went to the strata.

This is where we get to choose either a tri-Service summarization, which includes Marines, broken down by Service or, if we wish, we could just use each individual Service and look at their data separately, if we want to only choose males, possibly we just want to look at males under the age of 30, and maybe even just enlisted males under the age of 30, and see what

the impact of varicella is on that group, which is probably the at-risk group. I can look at this with calendar year.

You may have noticed some of these things disappearing as I made clicks here. The *x*-axis can only be those things that you are looking at all categories of disease. The secondary strata can be anything, and you have more than one disease. And I'll look at service.

We can perform a query. We get back all of the data, and we can view it any way we want. I'll just start with a line graph. I'll submit this query.

Again, this is what is downloadable, and this is what you can do remotely just with an internet connection. There is no Privacy Act data. There is no identifying information. It's just summaries of data.

You can see over the last seven years in this particular group of individuals, under 30 enlisted individuals across the Services, for this selected diagnosis, chicken pox, these were the rates per 1,000 person-years of disease. It's going down I think because of probably hospital admission practices more than anything else, but this is the actual data across the

military.

If we want to look at a table of this exact data, these would be the rates or we could just look at counts to see that there were 6,900 admissions for the varicella.

We can even look at the person-years, which constitutes this study population. These are person-year calculations. We haver data monthly going back to January '90 on the different Services. So we are able to calculate very accurate person-years of time.

So what might be of more interest is to look at everybody but then just break it down, rather than by Service, but look at age subgroups to see really where the burden of disease is in this particular group.

I can go back here since I no longer need to divide this. I can just say tri-Service data. I get the exact same answer.

DR. LaROSA: This is all coming off the AMSA site that you gave to us? That's how we can access it.

LTC RUBERTONE: That's correct. AMSA@ARMY.MIL. And then you can choose DMED and follow the links. It should be pretty intuitive. Anyone with a .MIL at the end of their e-mail is

granted an automatic password and user ID.

Anyone who doesn't have a .MIL, which may be a number of people in this room, right now we just review those. If there's any indication that they're affiliated with the military, we grant that pretty liberally. So I don't think anyone should have a problem. If you do, give me a call. And that allows you, then, to download the software.

Again, the younger age groups are the ones that are more at risk share the greater burden of disease for varicella, as you might expect, probably in the recruit camps.

DR. STEVENS: Does this calculate statistics as well?

LTC RUBERTONE: This DMED patient does not. This would just give the hospitalization rates and the counts or, in this particular case, the person-years over these different age groups in different years, et cetera.

This data is exportable. I can export this data. I can save the query, for one thing, but I can also export the data if you want to do further statistical analysis, whatever you can do with this data. I'll admit it's fairly limited, but I think it's a great way to get a quick

answer to something.

What Major Fisher asked us to do specifically was to look at vaccine-preventable conditions but then to look into the recruit population, as opposed to everyone else. That, for example, you wouldn't be able to do in here.

You can get a proxy for recruit by looking at less than 20 and maybe the 20 to 24 category, but if you really wanted to look at recruit status, we have to do that basically using the defense medical surveillance system, where we have date of accession and we can calculate a time that someone is a recruit, whether it's, of course, eight weeks or whatever fits into it.

I'm going to go back and do one other type of query that we can do, and that is our top ten diagnoses. What we just did was we selected a disease or a condition of interest in a population of interest and found out what the specific rates are.

But suppose we wanted to say, "I'm just interested in males, tri-Service." If I'm interested in males, what really are the diseases that they're admitted for?

We can't get a line graph or a bar

chart anymore because it's just a list of top ten. I can submit this query. We can see what the ten most common reasons for hospitalization amongst males in the military have been over the last seven years. I could have chosen one of the years, as opposed to all calendar years, if I want if I'm interested in one.

As you may expect, we've got a number of sports-related injuries, also some alcohol dependence. And adjustment reaction shows up on there, a number of other interesting things.

This one was the most interesting when I showed this to deputy surgeon generals because they couldn't understand disorders of tooth development or eruption, which is mostly wisdom teeth being pulled out. But they are hospitalized. So it shows up.

If I do the same thing for women now, as opposed to males, you get a kind of a different picture, as you might imagine. And most, if not -- well, eight out of the ten are related to something to do with pregnancy. There also do show up disorders of tooth development and often adjustment reaction. If you look at it just -- we do have a rate here of 4.73. I think if we go back to the males, that it actually is

lower. But just in the context of all the admissions, it comes out this way.

You can do this for all individuals and to see what the mix is or you can look at possibly just all individuals in the Navy if that's what was desired. This is it for all individuals. We try to list everything that the query pertained to. So I set off that question.

I hope everyone can see what the advantages of this kind of a system are. It certainly won't give you the definitive answer or study, but it can lead you in our direction or give you a view of the data.

The next thing that we look to do is to add a tab, change this, really, to hospitalization data, add a tab to have possibly ambulatory data, data related to deployments that we may have online.

Once we have this mechanism and just the real hard parts for figuring out how to have precalculated denominator person-time in order to calculate the rates, once we now have this mechanism, to add a tab and to add another category of disease is a relatively easy thing.

I believe that's it. I have about ten minutes left. Are there any questions?

MODERATOR FLETCHER: Thank you, Dr. Rubertone.

Questions, comments? Yes? Please identify.

CPT CLARK: Captain Clark.

How long is it updated? Is it updated on a daily basis?

LTC RUBERTONE: It depends on the source of the data. Our personnel data we get monthly. Our hospital days stayed we get monthly. Reported diseases we get every day. So it depends on the source. Most of the data for the most part is monthly, although we do get a large amount of data for HIV testing.

I just realized one of the things I didn't show is just because we changed the name of this. Let me see if I can quickly do this. It shows the numbers. So I don't really need to do it.

But we have over 20 million serum specimens in the DoD serum repository. It's the world's largest collection of serum specimens. And the advantage is that it's on a very fun population, which leads to individuals. We have many, many people with multiple specimens and serial specimens.

It used to be called ANSR, Army-Navy Serum Repository. But when the Air Force joined, we lost that wonderful acronym. And now we're called Serum. So that's why I forgot to show it for the demonstration. We have 20 million specimens that, for various reasons, were drawn and linked to them.

Any other questions?

MODERATOR FLETCHER: Questions? Dr. LaRosa?

DR. LaROSA: Two questions: one I think of great interest to many of us in the room who are not military, how to get a password.

LTC RUBERTONE: The answer to that is when you put your registration, just use the -- I'll just go to that page and show you. Just say that you are a member of the AFEB, and you will get a password, anyone who has any affiliation.

We have not turned down anyone yet, but if we decide to, we'd send out a friendly message saying -- you know, this is the AMSA's home page. And, as I said, you can look at all the MSMRs online. They're both in HTML and PDF form.

This is our latest one that people haven't even received yet. It's still at the

printer's. You can look at it. It's sent out. It's nothing more spectacular than with the cc, but that they're NOWR.

In any case, there's the febrile acute adenovirus. We'll hear about that a little bit later on today.

MODERATOR FLETCHER: Dr. Chin, I believe, had a question.

DR. CHIN: A comment. Members of the Board would remember back to I think the retreat session that we had with Dr. Joseph at Great Lakes, where we went into the injectors and the mission of the AFEB.

I think during that time, we created various sort of subcommittees or areas. One of them was the surveillance, which I think Dr. Elizabeth Barrett-Connors and I are co-chair of.

This presentation I think is very informative as to what has been going on over the past almost decade in development of this database and the ability to give integration and now the retrieval.

The real question still is: What is the role of the AFEB in all of this, if any? As I understand it, the way the Board is constructed now, we await questions from the military.

So the subcommittee is awaiting whatever questions or role that the Services would like. And I just would like to sort of emphasize that with the subcommittee searching for something to do.

EXECUTIVE SECRETARY FOGELMAN: Just to somewhat address your question, one of the subcommittees will be looking at one issue related to surveillance, which has to do with environmental hazard surveillance and just doing an overall look-see at deployment surveillance in general.

So as pieces get developed or partially developed through the military, the military will approach the AFEB to take a look at this and see if you have comments. And that's really pretty much the way we've been working so far.

Now, there may be some input with regard to DMSS in the future as well in terms of validating data that is collected or things like that, but that's the majority of this.

MODERATOR FLETCHER: Dr. Baker?

PROFESSOR BAKER: Do you get information on hospitalizations on shipboard?

LTC RUBERTONE: That's a good question

for the Navy. I mean, I don't believe the shipboard hospitalizations end up in the inpatient records. Does anyone have better information on that?

LTC DeFRAITES: They currently don't.

LTC RUBERTONE: I wanted to answer Dr. LaRosa's question. I'm sorry I didn't get to it directly. This is the registration form for the DMED. Here it just says there are some mandatory fields, but if you provide enough information so that we basically when I review it see that there are some military affiliation, as opposed to just a journalist wanting access, then you will be online and granted a password.

If you do have a .MIL on the e-mail, you will be automatically sent back a permanent password. Anyone who fills out a registration form is given a one-week temporary password to look at it.

There's nothing we're trying to hide. We just want to be able to control its growth if we should decide to take all of the expense.

MODERATOR FLETCHER: Dr. Perrotta?

DR. PERROTTA: A question and a comment that may relate to Dr. Chin's points, maybe even a comment first. Amazing. This is

really a great big step of things. In the almost five years that I have been doing this, we have been hoping that we would be moving in that direction.

For people who don't understand the entire process of the quality and the source and the limitations of the data that's in here, I would recommend if it's feasible for you and your staff to think about descriptions.

Let's say, for example, I'm interested in doing a study with Dr. Baker on ankle injuries and parachuting or something fun and we figure out where we can find that data. It's going to be really useful for us to understand what the limitations are.

Like you asked me for, are there shipboard hospitalizations on that? If we don't know what that is, we don't know exactly how good our interpretation would be on there.

So let me ask you that. Are you working on something like that?

LTC RUBERTONE: Yes. But the reason that doesn't exist today, because of the complexity.

DR. PERROTTA: Yes. I'm sure it is.

LTC RUBERTONE: But we are working

specifically for DMED to give a bit of a methodology document and user's guide to combine things. So what is this data that I should be looking at because it is non-exhibited? We understand that. We wanted to get something out there. And now we're trying to provide you with it over the internet.

And that will describe the type of data with respect, but it will never explain why the Air Force doesn't admit to alcohol, depression and the Navy does. You almost never will be able to explain that.

DR. PERROTTA: The second half is a recommendation for our consideration. And that is I'm so impressed with this as representing a huge step forward that I suggest that perhaps, Jim, your subcommittee do a more in-depth look at this and see whether or not we can make some recommendations about "Yee-ha" or "This is great news" or "Continue" or "More support" or whatever the Board would do.

I mean, I'm ready to say this is really a good thing, but I'm also smart enough to know that I probably ought to spend some time and manipulate my way through it and see whether or not it does the kinds of things that I'm hopeful

that it will do.

And maybe that's one of the things that we consider, a comment or some statement about this encouraging tri-Services of all nature to include their information, both medical and environmental, which I'd be interested in.

For your consideration, Jim. Thanks.

MODERATOR FLETCHER: Dr. Waldman?

DR. WALDMAN: Thank you.

Well, I think on the basis of the demonstration, it's fairly clear that it's a remarkable development. And that's great. You've shown us briefly a number of requests that people have made for information. So one question I have is: Whose requests do you honor, essentially? And how does one go about doing that? And to whom is this service made available?

I guess a corollary to that is that it wasn't entirely clear to me exactly what was available for the general public and which parts were not. There were some things that looked particularly enticing. Could you just break that down? You showed two different systems there. And I wondered which is which.

LTC RUBERTONE: Right. Well, the DMED

really is going to be -- just about anyone can sign on. It's a little bit governed by its growth. The DMSS, we've been successful at keeping it at a stealth operation. So we've honored all requests. We've never turned down anyone. Sometimes we've had to convince people that what they're asking for is not doable, and then we work with them.

But it probably will come down to having some kind of military collaborator if it's an extensive request.

DR. WALDMAN: Looking briefly through here, I didn't see any civilian requests on that.

LTC RUBERTONE: We have some. There are some studies ongoing. There's a Hodgkin's disease study that I'm aware with Harvard and Johns Hopkins. There are a few others. There's a prostate cancer study with the University of Washington, I believe.

So they are in there, but we right now probably formally have always had a military collaborator to help get involved. Especially when access to the data requires IRB and Human Use Committee approval, we certainly want the military to have a part in that.

But we do occasionally have some

drives to go along with their requests, just quick data, like "What's the race of something in this population?" That's not secret information. So we do give that out.

MODERATOR FLETCHER: Dr. Allen?

DR. ALLEN: I will echo the comments of others that this is tremendous. I came on the Board about the time that there was a lot of discussion about the Gulf War syndrome.

And one of the statements I remember to my absolute dismay being made during a presentation was that it wasn't even certain who all had been assigned to the Gulf War and where the records were and where they were when they were in the Gulf and so on.

Obviously to be able to try to sort out what was going on with people when you didn't even have a complete set of records as to who had been there and what potential exposure there might have been just was absolutely impossible.

This certainly in half a decade's time is just a tremendous, I hope tremendous, step forward. Obviously the proof is in the subsequent utility of it as we query and are able to get answers to the questions.

In particular, I think it's important

not only to use this as a retrospective database but to also look at the potential to use it for prospective collection of information; for example, as a study perhaps of vaccine efficacy is being done, the investigational vaccines that might be used to make sure that the serologic data are put into the database so that one can look at it prospectively as troops are assigned and have exposures and we can look at the information that's coming out.

So I think it's I hope got a great deal of flexibility and is going to be very, very useful for a lot of investigations and questions. I congratulate all of you who worked on this.

MODERATOR FLETCHER: Dr. Trump?

CAPT TRUMP: Dave Trump.

I've seen Mark's presentation before. And I, too, applaud the efforts that have gone on. I think for everyone here it's been alluded to, the issues of the quality of the data and the sources of the data.

This is a starting point for studies. I don't see this as a tool for studies. It's a surveillance tool, but I think all of you are aware of the limitations of personnel databases that have 2,000 individuals with unidentified

sex.

We don't have -- this is pulling together the existing data. And on the medical side, we probably don't have what you were mentioning as far as on the personnel side, the who went where for what great coordinate for what period of time. That's an issue that we're still developing.

So it's improvement, a lot of good data and effort. But with physicians making diagnoses, coders assigning the ICD-9 code, and someone along the line doing the data entry, from the DoD perspective, it's just a lot of -- look at this as the tool that it is, which is that it's a surveillance tool, but it's not the answer to any particular question.

DR. ALLEN: Well, the work involved in keeping something like this current on a prospective basis is incredible. And it's not going to be too many years down the line before somebody questions the cost-effectiveness of this if it isn't being used and very productive.

MODERATOR FLETCHER: Mark, how current is this? You may have said that, but I might have missed it.

LTC RUBERTONE: Most of our database

are very current compilations about two months old, personnel also about two months old. So we have data going back to the end of September.

Some data sources we actually get on an annual basis just because of more or less the source of that data. And that would be like the health risk appraisals. They do a lot of validation and Q/A until we get it in one lump sum. For the most part, it's very current.

I'll address this one thing that was mentioned about the cost. This is resource from hantovirus. We wanted the information as to the systems. The contract that maintains the system and keeps it all running; that is, if it just existed without any analysis, et cetera, is about a million and a half dollars a year.

MODERATOR FLETCHER: A question on that?

LTC AMOROSO: Paul Amoroso.

That really was what my question was, how many people are working in support of this, whether your resources are adequate to meet this.

LTC RUBERTONE: That's a good question. And it depends. For years, we sort of set our own functional requirements. And I have been preaching to just about anyone that we

really needed a strong functional proponency group for the preventive medicine community in DoD to start setting the functional requirements for this type of a system because a lot of people are going to see this. And their immediate not criticism but comment is, "Well, where is ambulatory data during deployment? Where is immunizations?"

Right now our resources are adequate for maintaining this and even for our growth that I have in migration strategy. If they were going to be used for prospective-type things, we could probably be under-resourced in our group.

MODERATOR FLETCHER: Dr. Jackson?

DR. JACKSON: I was at a seminar on Tuesday on phen-fen-related valvular disease. It provoked some thinking about high-tech and low-tech surveillance. The presenter went through at one point the list of things that were picked up by alert clinicians: hantovirus, pulmonary syndrome.

If you think about phen-fen, 2 million to 3 million people taking this, 30 percent valvular heart disease. What kind of surveillance system was in place to pick up something? The implications of this are just

astonishing.

I've always been intrigued by how we can somehow make much better use of the alert clinicians as stuff is coming up online and just by accident, some smart doc happens to see ten of them and say, "Oh, my gosh. There's something going on." How do we marry these high-tech to very practical systems?

I'm not on the subcommittee. I'd be interested in just some thinking along that line.

MODERATOR FLETCHER: Maybe let me talk as a cardiologist. I think this is really going to become a problem in the next few years here, all the people on phen-fen. I see one patient a month who has been on it.

The question about aortic valve and the other atrin triglyceride valves, -- and Dr. Haywood can certainly comment on this -- the public is panicked about this.

And then we listen to patients' hearts. We may hear a little murmur, the echocardiogram, which is technologically an unbelievable system that can pick up little leaks of valves that really clinically don't mean a thing.

And I think we have a major problem

here to sort all of this out and handle it appropriately. I think it's a very small, small, small percent that are going to have problems with these drugs. But I don't know.

Julian, do you have any comments on this?

DR. HAYWOOD: It can't pick up what you haven't been programmed to look at. So if you didn't set your surveillance system up to look at valvular disease, then how are you going to pick it up?

So there is a certain amount of anecdotal reference-based approach here. You have to be prepared to look at the system. And I think that means preparing the database to be prospective enough to be comprehensive. And there's a cost factor there.

MODERATOR FLETCHER: Absolutely.

Any other questions about this? Professor Eggert?

LTC EGGERT: Russ Eggert.

Mark, are you familiar with what was called the reportable disease database, the RDDB?

LTC RUBERTONE: Yes.

LTC EGGERT: Is that still in existence or has that been subsumed into the

DMSS?

LTC RUBERTONE: It exists for completely different -- I know you know most of the personnel for personnel purposes. And mostly looking at HIV and I think hepatitis B were the only reportable diseases.

So I'm not sure if the personnel community still has it. I've seen a flurry of e-mail about whether it meets with this. I don't personally think it does, but I can't really say.

I don't think that they would feel that their needs are being met by this system, to tell you the truth, from a personnel side, but I'm not sure.

LTC EGGERT: Well, I would say, if I may add, yes. As far as I can tell, it seemed to be blood-borne pathogens in kind of a laboratory-based system of reporting, which brings up the question: What about laboratory-based surveillance in support of things like global emerging infectious disease surveillance and the possibility of expanding DMSS to do that?

LTC RUBERTONE: We are talking with Dr. Diaz and Kelley about what, if anything, could be done for laboratory-based surveillance.

I think there are some automation issues in the DoD or we would get comprehensive laboratory-based surveillance right now. If it was available, I would say it would fit very nicely into the system.

We've got to decide what we've got to do, only accept sentinel locations to do the surveillance, probably going to surveil for all possible things, CDC, et cetera, or just select information.

So when that's worked out, I think there is a role for the DMSS to have laboratory-based data.

MODERATOR FLETCHER: Another question? Yes, please?

COL EITZEN: Mark, do you see this possibly being used if we had another ODS tomorrow and we're thinking about different exposures that people might have in that kind of environment, special vaccines, et cetera? Would you see a closeup of what you're doing now to incorporate the prospective part of looking at things like that?

LTC RUBERTONE: No. I don't think the type of questions that ODS is generating are going to be successfully met by this audit type,

but I think they're -- I think Dr. DeFraites was asked to look at a report of a higher rate of something in a group.

This rolled out into pretty quickly not only that group but a control group and possibly, a big possibly, sway the momentum that may get behind something that it's questionable whether there's actually something -- whether they're going to have all of these, as someone mentioned, coordinates, such as who was there, what the environmental parts may be, and a lot of other data I guess generated.

Colonel Fogelman?

EXECUTIVE SECRETARY FOGELMAN: Yes. As many of you are aware in the room, there is a new ambulatory data collection system that will be coming online for DoD probably within the next year or two. And I was wondering if there has been an effort underway to pull that data in.

LTC RUBERTONE: Yes. I have eight million rows of that, but it's only a few regions. It's not at every clinic.

EXECUTIVE DIRECTOR FOGELMAN: Right, right.

LTC RUBERTONE: So we do have areas that it is available right now.

EXECUTIVE DIRECTOR FOGELMAN: And that's a real critical piece that we were missing for a long time. So when we're able to fully collect that sort of data, I think it will be even more useful.

MODERATOR FLETCHER: Colonel?

COL DINIEGA: Yes. I'd like to just comment on something that Mark said a little earlier. This is Colonel Diniega.

He made a statement that one of the problems that we're having in medical surveillance and actually in the preventive medicine arena, prevention arena is the lack of a functional requirement. And that's a truism to the point that there's a floating requirements document called a SADR medical information plan.

And, as the Services provided their input to the team, it became very clear that the Army has a functional area in health service support that is labeled "preventive medicine," and the other Services did not.

As a result, as it got up to a DoD level, the preventive medicine requirements were thrown in with the hospitalization requirements, which I think is a misstatement when we get involved, thrown in with the inpatient and the

patient treatment centers. And I think that has to be sorted out before we can move on.

I think the Board could help in the long run if they were aware of the issue to come in correct with the nation or a statement that that should be sorted out.

That is one of the things we're beginning to see in the prevention arena, that we have not been looked upon as being separate. And we've always been second to something else.

MODERATOR FLETCHER: The time is up. We probably should move on. Doctor, thank you very much.

(Applause.)

EXECUTIVE SECRETARY FOGELMAN: Our next speaker will be Lieutenant Colonel DeFraites again. I won't reintroduce him, but he'll be talking to us a little bit about the implementation plan for DoD deployment surveillance.

LTC DeFRAITES: Thank you, Colonel Fogelman.

IMPLEMENTATION PLAN FOR

DEPLOYMENT SURVEILLANCE DODI

LTC DeFRAITES: This presentation is labeled in your packets as an update or a status

report on the implementation of a DoD instruction on joint medical surveillance. What I'm going to spend most of my time talking about is what's called a health surveillance seminar, which was our first well-orchestrated attempt to actually come up with the implementation plans.

It was hosted by the Joint Preventive Medicine Policy Group, which I'm the chairperson of, and also the J4, the Medical Readiness Directorate of the J4 of the Joint Staff. And that was Lieutenant Colonel Bob Thompson, who is also here today.

Can we have the next slide, please? The DoD instruction termed 6490.3 was signed in August of this year. And this instruction lays out -- I think that the Board has previously heard some details about what was going to go in that instruction, essentially in the pre, during, and post-deployment phases, a lot of the data collection that we've already discussed I think with Colonel Rubertone's presentation.

This instruction lays out essentially the requirement to go forth and do much better in terms of information gathering, surveillance, and prevention of disease and injury on future deployments. So our health surveillance seminar

was intended to develop some short and long-term strategies for implementing this thing.

A second objective of this seminar was to establish some sound foundation, in addition to the surveillance and prevention aspects, to also get at some issue of assessing of readiness of individual troops to deploy. That was the second objective, finally was to get on with some actions and milestones.

Let's go to the next slide, please. For purposes of our work, we divided ourselves up into four workgroups, into four shown on this slide. First of all, what we deferred, what we did not address specifically, were the issues of mental health assessment at that time and also the environmental issues, which were dealt with with a separate group, which I think the environmental subgroup is going to hear about this afternoon.

Go back to the previous slide, please. The four workgroups that we did have dealt with, our standard way that we do in a deployment, are disease and non-battle injury surveillance, both inpatient and outpatient settings. We worked from a joint perspective on an approach to reportable medical events.

Each Service, Air Force, Navy, Army, has their own system of reportable diseases, sentinel events that require reporting. And we wanted to work as part of a surveillance plan for deployments, a joint list, see if we could do that. And I'll talk to you more about how we're doing with that.

The third group dealt with these health readiness indicators; in other words, individual readiness from a health perspective, along with some measure by which we assess health before, during, and after deployment.

And, finally, the final group was to try to discuss issues of how all of this data was going to be handled as it's being generated and transmitted.

Let's go to the next slide, please. The first group. I'll just tell you a little bit about what we did.

Next slide, please. First of all, this group worked on a standard surveillance format. Right now there is essentially a directive from the Joint Staff to all of the combattant commands around the world whenever there's a joint deployment that medical surveillance in terms of outcomes, in terms of

visits to outpatient and inpatient facilities, is to be gathered in the standard format.

That memo, that instruction was signed in January of 1993. And it's been sort of the way we've tried to do business since then. And the purpose of this group was to try to update that, and that's what we did. We said that we reviewed the existing document and developed new categories. I'm not going to go into great detail on that today.

The second thing, in terms of the implementation plan, was to update the Joint Staff memo, to get another memo out and also to expand this concept to garrison; in other words, not just when you're on joint deployments but also when you're home.

That's outside the purview of the Joint Staff and the combattant commanders, and it's more the purview of the Army, Navy, and Air Force as we do business at home station. So it's a whole different set of sort of command authority that has to be involved in that. And that's been a tremendous obstacle to overcome.

Next slide, please. What we did with that workgroup was we think an improved surveillance format, where we incorporated the

concept not only of events of medical visits in different disease and injury categories but also emphasized the development or the calculation of rates on a weekly basis.

Some action thresholds developed based on the experience with these similar categories and similar outpatient experience at Camp Pendleton and other places where this has been used in garrison to get an idea of when we think a unit health care provider or unit surgeon needs to become concerned when their rate of event, such as diarrhea, crosses a certain action threshold. They need to look at it carefully.

And, finally, we made this, our new approach, compatible with something called EpiNATO, the North Atlantic Treaty Organization surgeons. The component countries or member countries have collaborated on a surveillance system that's employed, supposedly employed, during NATO operations. And we wanted our format, anything we were doing, to try to be compatible so it could be mapped into those categories. And we think we succeeded. And then, finally, we expanded our surveillance concept to try to include the inpatient data.

Next slide. What we had planned to do

was update the surveillance memo. That hasn't been done yet, but we're working on it to develop new forms and guidance to go with it and, finally, to develop an electronic data format to go with it as well.

And then the big issue, the big due-out, is to expand this routine-type surveillance to include appropriate garrison settings. And we thought possibly the way this could be marketed to units would be those units that are prepared to deploy that have their own organic medical assets, such as an infantry battalion with the battalion aid station. They would have a lot of interest in developing their baseline data in garrison to have something to compare with.

And, secondly, there's also the train to be prepared to implement this thing when you deploy by doing it all the time so you don't have to learn. There's no learning curve then.

Next slide, please. The second group dealt with the reportable events.

Next slide. The objectives of this group were, as I've already said, to develop a standardized DoD reportable disease list for use in garrison and deployments; and then to have one

specific for field use, if necessary, and then to recommend how this data might flow; and, finally, to identify what resources and what implementation strategy might be needed.

Next slide, please. By the end of the week, they had developed their first list, first draft of a list, of reportable events. And you can see in the beginning from their objectives to the accomplishments that the focus changed from diseases to events. And that's what I've been saying all along, that we should call it reportable medical events because it includes injury and some environmental issues as well.

Most of the infectious diseases were covered on this first draft list. And there were some outstanding issues that -- this group has met again and actually met yesterday and has gone through a second draft. And I think we're very close to having a single list of reported medical events.

We're not ready to talk to the AFEB or anybody else about it in detail. There are still some more issues to work out, but I think in the future this could be briefed to the AFEB with no problem. The rest of that I've already discussed.

Let's go to the next slide, please. This we already discussed.

Let's go to the next slide. The third group dealt with the health readiness indicators and the health assessment.

Next slide. The objectives of that workgroup were the following, as you see here: the readiness requirements, to somehow institutionalize them in op. plans, in operations plans, and SOPs, standard operating procedures, to give them significant, sufficient visibility and accountability, finally to get at some idea, some method that could be practical to assess and document the health status prior to the following deployment. This is one of the major I think obstacles or the challenges I think set out by the DoD instruction, how to assess health before and after.

There have been a lot of calls for our ability to do this. And we're still wrestling with how to do this in a practical way that has any meaning, to assess the health status as people are looking for ways to have capability to look back and determine what a baseline health status before a given deployment was and how the health status may have changed.

And, finally, it was to integrate this sort of health assessment approach, a concept with what's called the Service member life cycle concept. And under this concept in the information management is tracking an individual with information from the time that person is accessed into the military, through his training, through his deployments, through hospitalizations, et cetera, medical events that occur, personnel data, all the way through retirement or discharge from the Service.

I think you saw some of that concept laid out in Dr. Rubertone's slide. Essentially on a time line, if you view that as a time line from accession to retirement or death, then that's the information management Service member life cycle concept. We see that's pre and post-deployment assessment as meeting, requiring integration with that larger concept.

Next slide, please. The accomplishments of this group at this particular seminar were they did develop some consensus on some health readiness requirements.

They laid out a plan for what they felt was longitudinal health assessments. Really, what the concept is is they have a very

simplified pre and post-deployment assessment that can be done as needed right before and right after deployment.

The most important thing was to have some sort of routine periodic health assessment initiative. What we looked for as a model is a combination of self-reported health assessment that you get from what's called a HEAR, a health enrollment and assessment review, instrument but given on a more periodic basis to where that could probably be functioned as a much better baseline than something given at the eleventh hour before one would get on an airplane and deploy.

We think it would probably be a better, more accurate baseline to also have an opportunity when administered on a non-emergent basis, on a routine basis to get into more detail with issues that really need to be explored. I think a particular sensitivity is some of the mental health issues, perhaps some of the alcohol issues, and other risky health behaviors.

The other issues that were included in this longitudinal health assessment are some periodic tuberculous skin testing protocol. The group arrived at an annual schedule for that.

That is subject to change and also to get an HIV serum done within 12 months before deployment. Already for overseas deployments, the Services have some sort of limited requirement for documentation of a negative HIV status.

The DoD instruction on deployment surveillance requires for certain deployments you have serum drawn before a deployment, to have some serum available for testing if necessary.

And the idea here was to use this HIV serum that already goes into the repository, is already accessible through the defense medical surveillance system by name and by date, is listed very well, if done on a regular basis function as a good baseline serum and perhaps in some situations could also function as a post-deployment serum as well depending on what particular disease or reagent of interest you were interested in trying to use this serum for.

I think there were some differences in Service policies in terms of timing of HIV testing. And we're trying to work to standardize that among the Services more to make this HIV serum viable as this baseline serum for deployment.

We also came up with a condensed form

and questionnaire, very valuable input from the surgeons' representatives from the combattant commands. The CENTCOM, Atlantic Command, ATCOM, Special Operations Command were all there and felt, really, they could probably support a very brief questionnaire, both pre and post-deployment, very abbreviated. And what we're looking for is really in order for this concept to work, we do need some periodic health assessment that's much more robust than these brief questionnaires.

Next slide, please. Some of the issues, the due-outs from this group were to update the joint regulation on immunizations to reflect some of the changes. Mostly this reflects the focus on readiness that this group had in order to change some of the timing of the immunizations to be more standardized among the Services, especially with vaccines that have come online since the latest update of that joint reg, which was in November of '95. Since then, we've prepared the hepatitis A vaccine for one thing to come online and also the varicella vaccine.

We did set out as a plan to develop a joint regulation on deployment surveillance. In other words, instead of developing three Service

plans, Army, Navy, Air Force, for implementing, this DoD instruction is to have one. And that's what we're working on right now.

We actually met yesterday to further a draft document that Lieutenant Colonel Thompson, whom you heard from earlier this morning, has drafted a draft implementation instruction for the Air Force. And we would like to turn that into a joint instruction.

What we would like to have in that instruction, two main things, are to define these minimum health readiness requirements that both operators and medical people could support and, secondly, to try to codify or at least institutionalize this whole concept of some sort of periodic health assessment that could be used as a baseline for deployment surveillance.

Another objective was to integrate the idea of deployment surveillance into the Service member life cycle concept. This mainly speaks to the issue of how this issue will be dealt with in the development of new information management systems within DoD health affairs to try to get our seat at the table in order to get this concept at least recognized so that it becomes institutionalized as the Service member life

cycle concept goes forward.

And, finally, it's to integrate some sort of deployment module or travel history module into the HRA, the health enrollment assessment, review as it's developed. Right now there is no deployment-oriented module in the HEAR.

Next slide, please. The final group on network and health data: collection and transmittal.

Next slide, please. They dealt with issues of two things. One is how to transmit data, in and out of fear as these joint performances have gone on; secondly, how to get specimens out of the data. If you're going to draw this close to deployment serum as mandated, certain deployments, then if that's done in data, how are you going to get it back? And how are you going to get it registered in the record?

So they dealt with the idea of the questionnaires of serum, the data flow. We asked them to be very specific about performance of contact. And that's all going to be codified into our joint recommendations.

As Colonel Diniega mentioned, the theatre medical information program is to develop

a plan for integration of some of the issues in deployment surveillance into the medical informatics program. We've had input into the theatre medical information. Colonel Fogelman gave some functional requirements that came out of this seminar into the program that's working on the theatre medical information project.

Next slide, please. So we've done some of that. The other accomplishments of this group were they did identify the process, and they identified the points of contact.

Next slide. There were quite a few due-outs from this group in terms of nice things to do. And one of them was to overall get surveillance report and reportable disease form incorporated onto the Armed Forces Medical Intelligence Center's CD-ROM in MEDIC.

I think this group has seen that demonstrated. It has medical threat information and countermeasures. One of the issues is we'd like to see some of these forms also included on that CD-ROM to be available for everybody to be able to get at those. And, secondly, we could have a Web page access to some of the forms as well.

In terms of these completed forms, we

view that these pre-deployment questionnaire problems need to be completed at home station and the post-deployment questionnaire probably is best completed in theatre.

And, finally, we felt the pre-deployment obtained from HIV, the post-deployment, the timing, and location of this post-deployment specimen, if needed, where it would happen is unresolved as of the end of our meeting.

Now, it's a very significant logistical problem for a combattant commander to be able to support that type of operation in some sort of sparsely supported theatre. So it's still an issue that's not resolved.

This idea of having the HIV serum specimen function, both pre and post, I would say has not been accepted outside of our group. So it's still an open issue. And probably the informatics automation is also an issue.

Next slide, please. These I've already said, the completed tasks of the group.

Next slide, please. And the action items, I've pretty much addressed all of those. Unfortunately, I didn't have these slides available on paper. We can get them printed out

and issued by the end of the day. I think we can get printed.

Some of the due-outs that I hadn't really talked about in great depth, environmental surveillance work, there was a separate group that was addressing these issues specifically.

And also in mental health I think there were very significant issues that our group that met in October did not feel we had the expertise, really, to address them. But that's a very large -- both of these are big parts of the DoD instruction on medical surveillance. And they're going to have to be dealt with at some point.

Finally, always the reserve components, how they're going to play and how they're going to be able to participate in reserves also needs to be integrated, too. We felt that at a higher level, this issue of post-deployment serum needed to be resolved.

And, finally, also, as had been alluded to earlier, we're very much at the mercy, the DMSS I think is very much at the mercy, of the quality of the data that's being collected for other purposes.

One of those very significantly for

any type of deployment surveillance is the personnel data on who is deployed and when they enter the theatre, when they leave. And that is not a medical database, a personnel database.

And we have had some discussions with the personnel managers in all of the Services. Again, each Service has their own way of doing business. And each one is sort of evolving at different rates over time. So it's been a very hard issue to keep current on since all the Services are operating somewhat differently.

Really, all we can do from our vantage point is just to bring it up as an issue that we have a vested interest in that someone else needs to fix. Unfortunately, we don't have the authority nor the resources to fix it.

Finally, it is to try to do what we can to accelerate the automation support for operational medicine so at the aid station in the deployed setting, automating all aspects or as many aspects as possible of operational medicine would greatly assist us in our attempt to try to keep track of what's going on.

I think that's my last slide. Yes, that's it.

MODERATOR FLETCHER: Thank you very

much.

EXECUTIVE SECRETARY FOGELMAN: Any questions?

MODERATOR FLETCHER: Questions or comments?

COL SANCHEZ: Yes. Colonel Sanchez from CHPPM.

How is that proposal flowing to the data? Is this intended to go hard copy now to the disease surveillance team and then in data form to the AMSA? How is that going to work out?

LTC DeFRAITES: Yes. Yes, sir. I'll repeat it. Right now the concept is that this data at the very brief -- I didn't show you the readiness indicators. I didn't show you the questionnaires, the very brief, one-page, questionnaires.

Right now the concept is you get down in paper format, their sense of the deployment surveillance team. And then the data is transmitted to the deployment, DMSS.

So the data from those pre and post-deployment questionnaires is intended to go and to be incorporated into something like this at the Center for Health Promotion and Preventive Medicine.

We would like to go to an automated system.

COL SANCHEZ: I was thinking the Web. You mentioned the Web. We could access it through the Web.

LTC DeFRAITES: Yes. That would be the ultimate way we would like. It would be a lot faster I think to process people. And also the data would go into the process and wouldn't get lost.

MODERATOR FLETCHER: Dr. Haywood?

DR. HAYWOOD: How are confidentiality issues being handled?

LTC DeFRAITES: Confidentiality issues of?

DR. HAYWOOD: Personal data, HIV.

LTC DeFRAITES: The HIV data is already protected. Their data system -- I can well describe it now, but it's a secure system for HIV status of the serum. And how to get access to the identifiers for that serum is under the control of the defense medical surveillance system, but it's not accessible. There are additional fire walls in place to protect the confidentiality.

Confidentiality of forms for Social

Security, numbers, and names in the mail is no more confidential and protected in mailing boxes of forms through the mail than it is for any other piece of mail.

All the databases that have personnel identified have got requirements that for confidentiality, we have personal identifiers. So all of these data systems you see that are linked by Social Security number or name, there are laws in place.

MODERATOR FLETCHER: Questions?

EXECUTIVE SECRETARY FOGELMAN: Dr. Reingold?

DR. REINGOLD: I was a little confused in terms of the questionnaires about health status, whether the plan was to do those pre and post-deployment as well as on some sort of regular basis or to use the ones done on a regular basis in place of pre and post-deployment or what.

LTC DeFRAITES: What we envision is a little of both, that on a routine basis to go in great depth about the assessment of your health, both more of a periodic health assessment, like a health risk appraisal, and some sort of limited medical review on a routine basis, and then pre

and post-deployment a very limited amount of questions that announce things like, "Has anything recently happened to you that we need to know about before you deploy? Are there any questions or concerns you have right now?"; just sort of being a very brief and concise update.

But the time to go into great depth about your alcohol use, any other type of medical problems that you might have, that's where we see this periodic health assessment being the opportunity and a more appropriate place to do it, rather than doing that at Fort Bragg right before you get on an airplane to go someplace and also when you're coming back.

DR. REINGOLD: Yes. But I think the other important point is if there's going to be any attempt made, for example, to compare the important health status of people after a deployment versus people who haven't had that deployment.

Clearly the data will be much less, probably will be more objective and less biased if they reflect on a regular basis, rather than immediately pre and post-deployment. Then we won't have data post-deployment or pre-deployment for people who weren't deployed.

LTC DeFRAITES: Yes. That immediate pre and post-deployment brief questionnaire, of course, you won't have that on people who didn't deploy, but you will have the periodic routine health assessment data on everyone.

That's the only basis you're going to have for any sort of comparison. But, really, that's where most of the important information is going to be anyway. It's not going to be in this short questionnaire. I think it's much more validated, and it's simply much richer anyway.

MODERATOR FLETCHER: Dr. Sokas?

DR. SOKAS: I was just going to ask who administers those questionnaires and who enters the data, then.

LTC DeFRAITES: Which one?

DR. SOKAS: Either the routine, more complete health assessments or the limited pre and post-deployment questionnaires.

LTC DeFRAITES: Limited pre and post-deployment assessments, I mean, it could be a number of settings, but anywhere from in a battalion aid station, like clinical setting, to a deployment line, when you're going through and getting your will updated, and your emergency information and then you sit down to fill out

this thing.

DR. SOKAS: So it's self-completed?

LTC DeFRAITES: It's completed, but then there is a requirement to have some sort of medical review of the answers that are given. And then there's codified in it what type of responses require higher medical review.

DR. SOKAS: Okay.

LTC DeFRAITES: So if you answer "Yes" to the question that you might be pregnant and you're a woman -- if you're a man, I don't know. We go back and ask you again. But if you're a woman and you are pregnant or might be pregnant, then that requires a little bit more medical review of that answer, something like that. That right now is the way it's done.

I mean, that data, the way it was done for Bosnia is supposedly the original station, the medical record is a piece of paper in your individual patient record. And a copy is sent back through the mails now to the deployment surveillance team. And then that data is put in, entered at that point.

But that's more of a routine medical clinical setting, where you come in and have a medical review. You go get your personnel record

reviewed, and you come and see the doctor or the medics and have this thing filled out.

Then that data, there are plans in place to have a preventive health care system which automated that process and have routine health assessment. Once that data is made automatic, then we can talk about incorporating it into a DMSS.

Already Colonel Rubertone said he's got health risk appraisal, which was the Army's precursor to this present DoD health risk appraisal, but the old Army health risk appraisal was in a scannable format.

There is some self-reported health risk behavior-type data available. This will be much more comprehensive, I think. That's the idea, I think. That costs a lot of money to do it.

MODERATOR FLETCHER: Other comments or questions?

(No response.)

EXECUTIVE DIRECTOR FOGELMAN: Thank you.

MODERATOR FLETCHER: Well, thank you, Colonel.

(Applause.)

EXECUTIVE SECRETARY FOGELMAN: Well, actually we have three speakers for the next talk, which is going to be an adenovirus update. We're going to have Colonel DeFraites stay up front on the block to open with an introduction.

Then we'll have Colonel Jose Sanchez, who's the Chief of the Epidemiological Consultant Service in the Army; and Lieutenant Commander Meg Ryan, who has briefed you before, who is the head of the Preventive Medicine Department for the Naval Hospital, Great Lakes.

We'll start out with Colonel DeFraites.

ADENOVIRUS UPDATE

LTC DeFRAITES: Yes. My part will be very brief because you heard an update on the status of the adenovirus vaccine in August. And I'm going to just give a brief update of where we are now.

Next slide, please. If you remember, there was a two-pronged DoD approach to addressing the issue of the end of available adenovirus vaccines. And the first one was to extend the supply from Wyeth.

And our plan was to administer vaccine only during the winter months, between September

and March. In order for that plan to work and to be translated into an extension of available resources that Wyeth, the manufacturer of the vaccine, had to request an extension of the shelf life from the FDA.

When I briefed you in August, I said that that was pending. Well, that remained pending, really, for another six weeks after I spoke.

The second prong, the second branch or action that's part of DoD's plan is to participate in development of a new vaccine source.

Next slide, please. In terms of the extension of Wyeth vaccine, we do have an extension from the FDA through August of next year. However, as I already mentioned, the delivery of vaccine this year was delayed to the recruit stations.

And, actually, I think -- well, Lieutenant Commander Ryan and Colonel Sanchez will talk to you specifically about issues at Great Lakes and at Fort Jackson that are related to that. And they probably have specific dates at which vaccine was received, but it was closer to the beginning of October than the first of

September.

They will also be describing these outbreaks of adenovirus, of acute respiratory disease that's mainly attributable to adenovirus at at least these two sites, Fort Jackson and Great Lakes,

Next slide, please. In terms of a new adenovirus vaccine, right now we have no contract with any manufacturer. Yes, we have a contract with no manufacturer or no contract with any manufacturer. So nada.

And the cost estimate, what's happened is the manufacturer that had expressed interest and had proposed development of the new vaccine was Grier. Their estimates of the cost that they would incur, the risks, the financial risks, that they would incur have escalated. And there are still negotiations with the DoD with the manufacturer. That's really all I'm prepared to say about that right now.

Next slide, please. I think I'll turn it over. Colonel Sanchez, are you next or Commander Ryan?

MODERATOR FLETCHER: Any questions?

CDR McBRIDE: Bob, I have one comment. The FDA extended the shelf life -- this is Wayne

McBride -- until August of '98. But we will have supplies that will last us belong that. What is the effort to extend the shelf life gets further to allow us to use what will yet be remaining after that extension is expired?

Do you know what I'm trying to say?

LTC DeFRAITES: Yes. Wayne, I'm glad you asked because the issue is going to come up again this summer that FDA -- why it is incumbent upon the manufacturer that it meets your request for another extension.

In order for us to use what we think, our projections of vaccine availability, if they hold up, we have enough vaccine -- if we use it during these months at the same rate we have in the past, we think we have enough vaccine to last until through the Spring of 1999. So it would behoove us to request that Wyeth extend the shelf life.

And our agents I guess at DPSC already know that this is going to be something that needs to be done. And all we can do is work with the manufacturer to provide data to FDA. But it's really incumbent upon the manufacturer to request it.

DR. ALLEN: What biologic or

laboratory data is supplied to the FDA to support the request for an extension?

LTC DeFRAITES: I don't know that. As a matter of fact, we really were not -- I personally was not party to seeing that data. FDA protects the confidentiality of negotiations between them and -- they view it as an issue between them and the manufacturer. So I don't know what data was provided and what data FDA needs.

DR. ALLEN: Presumably there are hard data that underlie that request. It's not just a "We think it's probably okay. Please extend it"?

LTC DeFRAITES: I can't answer that. I don't know.

EXECUTIVE SECRETARY FOGELMAN: Dr. Gaydos?

COL GAYDOS: Joel Gaydos.

I believe that Wyeth is sending them real-time testing potency.

COL SANCHEZ: It's a pleasure to be here with you. I'm Colonel Sanchez. I used to be assigned to this administrative detail this summer. Now I'm at the CHPPM, the Center for Health Promotion and Preventive Medicine, working with the surveillance guys.

Before I start, this will be more or less of a canned presentation. There will be a handout later on available in the desk. I will also encourage you to get into the Web site and look at the latest report on the November issue of the MSMR, medical surveillance monthly report, that Mark Rubertone puts out because there is an excellent report from the field.

Having said that, today I would like to present to you the results of an epidemiologic investigation conducted among Army recruits at Fort Jackson, South Carolina. This is what we call an EPICON investigation. It was conducted with the assistance and support of medical officials from the institutions listed at the bottom of that slide.

Namely I would like to credit Lieutenant Colonel Rose Marie Hendrix and Colonel Dale Carroll, the commander of the hospital, at Walter Reed namely Colonel Bruce Dennis, Dr. Lenny Binn for providing the virology, part of the virology work done by Lieutenant Colonel Pat Kelley. And at the supporting medical center, the Dwight D. Eisenhower, Colonel Mills McNeill has been tracking this epidemic or this problem since it started.

Now, during the Summer and Fall of 1997, a slow but consistent upward trend in febrile acute respiratory disease rates was noted at Fort Jackson by officials at the ARD surveillance program here as well as by the preventive medicine officer locally, Lieutenant Colonel Hendrix.

Coincidental with this relative increase, which, by the way, has never exceeded the threshold for the whole post of 1.5 percent per week, was the initiation of an adenovirus surveillance study by Dr. Greg Gray and his collaborators from the Navy Health Research Center.

It should also be pointed out and important that routine immunization of recruits as mandated by Army policy ceased or stopped this year in 31 March 1997. And it was not restarted until 3 November 1997. So the data that I will present to you here is while in the absence of an adenovirus vaccine.

The principal objective of the EPICON was to collect appropriate serum and throat swab specimens for culture from ill recruits that were hospitalized at the infirmary of Moncrieff Army Hospital at Fort Jackson.

This was done to support what's called the adenovirus replacement program, or ADREP in your slide, and the work that's been done or started by Dr. Binn here at WRAIR.

Obviously another and probably more important objective was to assess the impact that these acute respiratory diseases or adenovirus infections have had on the military recruit training population at Fort Jackson. Hopefully by defining risk factors for illness, we could maybe come up with in the absence of vaccine some non-vaccine preventive measures that may help in controlling the transmission of these agents and possibly help us plan for future studies, both vaccine as well as other integrational studies.

Now, Fort Jackson is located in the city, outskirts, of Columbia, South Carolina. And it's a center for basic training for over 50,000 Army basic trainees a year. It is the largest Army training post.

Within four days of arrival on post, recruits are in process at the United States Army Reception Complex. And among other things, besides getting their uniforms and being told how to salute and being dragged around by the drill sergeants, they also get their medical and dental

exams, what's called a troop medical/dental in-processing reception clinic.

Now, part of that in-processing involves immunization. And one of the vaccine preventable agents that we immunize against is adenovirus Types 4 and 7.

Now, this vaccine again is routinely only administered during the October to March time frame, coinciding with the administration of each year's influenza vaccine.

The way this works out -- this doesn't show well, but this is a ward. This is a hospital ward, could be anywhere. Any recruit that presents to the Battalion A station of the troop medical clinic with a temperature, oral temperature, of 100.5 or greater and one or more symptoms of respiratory illness is automatically admitted to the ward, to the infirmary. It's called the ARD infirmary.

Now, upon hospitalization, routinely within 24 to 48 hours -- and this is done serially overnight, the next morning. If it's Monday through Friday and it's done Monday morning for those recruits that got admitted on Saturday and Sunday, the infirmary staff -- and this is Mrs. Joanie Connolly, the adenovirus

study contract nurse, which collect clinical data and samples on all patients for a viral workup.

Now, it is upon this already existing system that we piggyback ourselves with additional personnel resources for clinical evaluation of patients as well as collection of blood samples, which is not routinely done by the adenovirus random study, as well as collection of clinical and epidemiologic data.

Now to the findings. A total of 79 patients hospitalized with febrile acute respiratory seizures were seen and evaluated during the 10-day period at the end of November.

Sixty-two percent of these cases were males. This closely matches the actual distribution of recruits at Fort Jackson, which for this year is 61 percent men and 39 percent women.

Only 3 of the 79 soldiers that were evaluated had actually received vaccines. They had just come in, and they were like the first or second week of training and had just received vaccine. I remind you the vaccine was started on 3 November.

Main symptoms include fever, headache. We included two additional patients which had

reported a history of fever, but when actually measured on admission was not 100.5. So that's why this is not 79. It should have been 100 percent technically, but be that as it may.

Now, an important component of this illness were these nasty looking tonsils or adeno tissue, which covers quite a significant amount of this comport, as you might imagine from the recruit standpoint.

Around two-thirds of patients; that is, 62 of the 79, 62 percent of the 79, were in their 5th, 6th, or 7th week of training. Very few actually were seen during their first three to four weeks and very few in their eighth week.

Their AIT is a second training period after their basic training, where they actually get specialized training in whatever occupational specialty they go into. I won't go into too many details other than that.

Now, when you look at the review of the path data for the period of May through November '97, you see that a majority of cases occurred in the fifth to seventh weeks of training. Let me take you through these slides.

These are actually the confirmed positive adenovirus results. I have data here

and going 265 isolates. These are not all the isolates. An updated figure you'll find in the MSMR report from November. You can look at that.

Actually, these are the weeks of training. So these are the differing units. Each of these lines are different companies. And there are either four or five companies per battalion. There are 8 training battalions, a total maximum of 40 training companies. Each company is about 200 individuals on the average depending on the time.

This is week one of training, not much happening. Week two, not much happening. Week three, you expect to see a blip in this unit second of the three nights. On week four, another blip. Blip on here, week five. Another blip on week six. And two large clusters on week seven. Not much on week eight. And this is arbitrarily week nine. That's actually unknown information. Now, that's the adenovirus isolate.

Now, if you look at the whole ARD population -- and I'll tell you later what percentage of this ARDs that were cultured were actually adenovirus-positive.

Be that as it may, when you actually look at the clusters of all acute respiratory

diseases -- and these are clusters. The background here in purple or dark blue is two or less cases. This should actually read zero to two. Okay?

So anything with three or more cases we called a cluster arbitrarily. We thought in a company-size unit, three or more would represent a 1.5 percent or more. And that remains the threshold.

There are 32 separate clusters. And all of them mostly with the exception of this cluster here and this cluster here occurred in weeks five, six, and seven while individuals were undergoing weeks five, six, and seven of training. That's the overlap. You put these things, such as the ARD. And this is the significance. This all happened in weeks six and seven.

Now, this is sort of a summary. After review of all of the available data, we identified 12 separate clusters of adenovirus-confirmed illness, 3 or more cases during the period of August to September. I do not have complete data yet for the months of October and November. So there will be a few more identified, I'm sure.

We identified the possible introduction of adenovirus into basic combat training units by affected new recruits in at least six instances. I'll show you that in graphical format.

Three companies had 16, 18, and 19 adenovirus-confirmed cases, respectively, for an attack rate for adenovirus-confirmed respiratory illness, hospitalized, of 8 to 10 percent.

In addition to that or on top of that, if you only look at ARD, there were 32 separate companies during the summer and fall that had rates that exceeded one and a half percent per week, 5 of which exceeded 5 percent per week.

For some reason, we're not sure why the rate, the ARD rate, and not the adenovirus virus rate but the ARD rate, was higher in the first training recruits. As expected, rates were lower in the reception station troops or in troops that had already gone by basic training and they were in their advanced individual training.

And when we look at starship, those troops that were based, housed in starship barracks versus those that were housed in other barracks, we call them rolling pin. I'll show

you a photograph later. There was no difference in ARD for adenovirus rate.

These are the 12 ADV clusters. These are the respective 16, 18, and 19. Each one of these peaks is a separate company for a separate week. There are 12 of these clusters. These are the companies running this way, 40 of them.

And these are the dates starting from early May, June, July, August, September, for the start of October. So everything is happening late August, bulk of September, and early October, the majority of cases occurring in the first week, where they had a higher rate.

These are the introductions or the seatings or whatever you want to call them. I tried to superimposed that. There were nine individuals that were picked up as adenovirus-positive.

During their reception week, when they initially came to Fort Jackson, three of them fizzled out. They failed. They were chaptered out or whatever. They didn't go on to become part of basic training. They just went home, those three individuals, these three arrows.

The other six went on to different units at different times. In three of those six

instances, mainly here, here, and here, they preceded immediately before an outbreak in that unit, that company that they went to. That doesn't mean that they were in that phase. It could be that there were other stages at other times. Certainly I think it illustrates the point of the risk of introduction of the virus in a population.

Now, I show you 12 mountains. That was adenovirus. These are the 32 mountains for the ARD. Each one of these cups is cut at one percent. So if you go past the brown, that's already past the threshold level.

Thirty-two times, 32 separate instances, there were companies that exceeded one and a half percent per week incidence of acute respiratory disease, fever after respiratory disease. That means hospitalized, not just any fever.

Of those that were cultured, -- and I got information on 265 isolates out of 814 individuals cultured -- 33 percent of them were positive. Again, as expected, high rates of isolation of adenovirus in the training units, as opposed to the individuals recently arrived or individuals that are more experienced, have

already gone through basic training. We call them AIT.

Now, the average time taken away from unit -- and this is actually what drives home the point to the commanders, not what I showed you before -- due to adenovirus infection was estimated to be about three days. You will see later it kind of matches with the experience that the Navy at Great Lakes has had.

If you look at the actual impact, you can tell that approximately 800 man-days -- this is one battalion. All right? This size unit was lost from training because of adenovirus-confirmed. It's not all ARD. This is just those that are confirmed during that five-month period between May and September, probably twice that if I include October and November data whenever I get it.

It doesn't show well, but this basically prefers to show a cross-sectional survey of two of the affected platoons. And this is Mr. Turley, who is in the back of the room. He's here administering a questionnaire. We were trying to look at risk factors for illness.

To make a long story short, 122 trainees were interviewed. The only possible

risk factor for reporting on acute respiratory disease illness was being female gender. That may be an artifact of reporting, may be more likely reporting by females. We don't know since we do not see a predilection, as I showed you, in our missions in terms of the rate for females versus male. We have yet to see if this shows up in other studies.

There were no clear associations with hand-washing practices and other personal hygiene factors or a prior history of smoking. What is important, though, is that although hand-washing practices have been emphasized, has received a lot of high-level command from the general down, only three percent of individuals interviewed in those two affected units actually reported knowing about it. Basically the word is not getting down to the user level, from the drill sergeant down to the recruit.

Now, industrial hygiene ventilation surveys were performed in starship -- this is what they looked; again, this is why we call them starship -- as well as in rolling pin, rolling pin because if you look at this from the top on a map, it looks like the pin of an M16 rifle. You're going to have to believe me on that one

because I still don't see it.

The point here is that when you actually go in and measure -- this doesn't show well, but we actually place in four different platoons, two in starship barracks setting and two in this other type of barrack setting, and we actually monitor it throughout the weekend and then through the week while they went to sleep and then went home.

Actually, what you find is an excess. If you measure level of carbon dioxide indoors, it tells you a measure of crowding. And for a number of reasons, NIOSH has set up the threshold at 1,000 parts per million. So if you exceed that level, you are already violating NIOSH's standards. All right.

Those levels were reached and exceeded every day, whenever it was measured. It didn't matter where we measured and what type of barracks. It did not matter if we were doing it, if the females were sleeping, if the males were sleeping. They all were exceeded. I'll show you that.

It was similar in both types of barracks. All right? So that was not different. And usually that threshold was exceeded whenever

you reached about 40 recruits sleeping in that area, 40. It looked like it hit that threshold at about 40. And it happened.

You actually measured this in 15 minutes. You can actually set it up to measure every 5 minutes if you want, but we did it every 15 minutes for the whole period of time.

This actually doesn't show what purports to show that there are more than 40 individuals in there. This is actually measurement in one of the units.

These are actually 43 males sleeping there. You're going to have to believe me, but this is about 8:00 o'clock. This is the CO_2 level. They're out training in the field, so not much going on.

The parts per million are rounding about six, seven hundred. All right. Then it picks up. They come in all hurrying. They want to go eat, take a shower. So it exceeds about 8:00 to 9:00 o'clock. Then they go to sleep, they're all breathing in their air and so forth, at about 1,000 parts per million.

Then a drill sergeant suddenly walks in and says, "Everybody wake up." Boom. And that thing shoots up at about almost exactly by

the time -- you can tell when that drill sergeant walked in the room because those guys really get nervous. And then, of course, they all empty the barracks or they go back to a level.

The same thing. It didn't matter what you looked, if those were males, these were females in the same type of barracks, starship. This is the Field 2 level here, right here, this thin green-looking one. So again a peak sometime in the evening.

And this was actually through the weekend. So this was actually Friday, the 21st; Saturday; Sunday; Monday. You can see the peak repeating itself and all exceeding. This is the actual threshold right here at about this level.

And then we went to the -- I'm not going to show you we had about -- these were just for illustration purposes. This was the non-starship type. This is the CO_2 level. This is the threshold right here at 1,000. And this is a graph consistently exceeding 1,000 parts per million.

So something's happening. That non-ventilation is there or we've got too many recruits for that amount of space or they're breathing too much or they're too nervous or

something or a combination thereof.

When you actually go in and you look at what's going on, you see that they're sleeping head to toe like they're supposed to. They're supposed to leave every other window open during the day and at night, even though it might get cold, to avoid this. But when we went in, we routinely and consistently, daytime or nighttime, found their windows closed.

They were also instructed to leave a large room fan, which is right in the middle of the bay area. And consistently it was found in the off switch mode. So if they did this, maybe it would help solve a little bit of the problem.

And herein lies what I think the problem and what we think the problem is. I think concerns about energy conservation -- and for those of you who can't resist it, you can read the large type, no problem. But this little line says it's totally opposite to what we're finding that is supposed to be done.

Wait a second. Is that "Keep windows and doors closed"? There's a problem here. Okay? This is actually what's posted in the barrack. Okay?

So you've got, on the one hand, the

engineer saying, "Don't waste my money and electricity"; on the other hand, the medical saying, "We've got a problem. You've got to open the window." All right?

When you look at the bathroom sinks, you see that, yes, there's a great amount of space there. They're as clean as can be because of the same reason the trainees don't want to use them because they don't want to dirty them. They don't want a drill sergeant to get after them.

And you don't find soap. You find the sinks in there, but you don't see any soap bars. So, actually, the hand-washing facilities are not adequate in the barracks. Yet, when you go to the field, the hand-washing is much better, ironically.

There's minimal mixing between companies. This is company-specific mixed training. So there's ample opportunity for interaction at the dining facility at noontime and when they come back at 1700 to 1800 hours, usually when they have their dinner.

At the hospital, if they visit the hospital at leisure time, recreational activities, usually on the weekend, mostly on Sunday. These guys don't get a lot of fun from

Monday through Saturday. They do get some time home, and their families can come and see them, usually on Sundays.

The important point here, there is actually mixing between platoons. This is mixed training. So actually what happens, even though the females sleep in separate platoons, each one of which is about 60, when they actually train, they take that platoon and take two squads of that platoon and two squads from the male platoon. And that's how they train. So during the day and dinner and everything, except for sleeping, they're together. Okay? Integrated training, as we call it.

This is where I think we're moving and some of the pending information that I haven't presented to you. Dr. Van and other collaborators here, Dr. Colonel Ennis will be looking at serologic antibody and anti-infection methods in support of the adenovirus replacement program. We're going to be looking.

I show you illness data. What I want to do now is look at antibody markers of exposure. Given that these were non-vaccinated individuals, if I find the antibody, it must be because they got naturally infected and not

because of the vaccine. So maybe I can look at that endpoint. We're in the process of doing that.

All individuals admitted to the ward will continue to be cultured with support. We need a little bit of money on that, the problem there. There is an opportunity to conduct future prospective epidemiologic intervention programs, selecting specific company-sized cohorts that may be comparing units in the first and the fourth training brigades.

We've got to look at environmental factors. This is something that John Broditch back in the late '80s and others wanted to look at in full scale. And for a number of reasons, that study never happened. We may want to survive that during the non-vaccine period next spring, next summer.

Last but not least -- and this is for me what I think is more informed from my standpoint -- is that we have good baseline data, at least two posts now, at Fort Jackson and at Great Lakes, that actually will serve very well to tell us what to expect in the future.

And if we come up and if it is required by FDA or whatever that we have to do,

vaccine efficacy, come up with vaccine efficacy, measurement studies that we have the population there, that would lend itself very nicely to that.

I'm going to stop there. I guess I can take questions now or we wait?

EXECUTIVE SECRETARY FOGELMAN: In the interest of time, it would be good if we could let Lieutenant Commander Ryan talk. And then we'll take questions at the end.

MODERATOR FLETCHER: Thank you.

LCDR RYAN: Well, thank you. I'm going to give you a brief brief on the experience at Great Lakes, which really does mirror the experience at Fort Jackson during this fall. It will be a little more low-tech than Fort Jackson's presentation to you, but we really did have the same challenges, actually I think on a little bit smaller scale.

To give you again the background, we have been using adenovirus vaccine without deliberate interruption for years and years in boot camp. And, actually, without doing it just in the wintertime schedule, there is -- so we had been using adenovirus vaccine without interruption for years, of course, at Great Lakes

and then when the crisis of the supply became apparent went to the wintertime schedule. So, actually, the first time that we at Great Lakes took a deliberate break from giving adenovirus vaccine was in June of '96. So we took a deliberate break during the Summer of 1996 to conserve supply.

Go ahead and go to the next slide. And, of course, the concern is what would happen to us. So you can see we did not use the vaccine between June and September of 1996. And then we restarted it for the winter.

Then we took another break, which is -- the time when we're supposed to take the break is April, April to -- it's supposed to be September 1st.

And then we had this delay waiting for the approval of the shelf life extension until October 15th. Actually, we started October 16th, a little before Fort Jackson did. And we started for the winter at that time.

My little asterisk at the bottom there says that there were some breaks in the use of this vaccine that were not deliberate prior to this vaccine crisis. In fact, we had a problem with supply during the Winter of '94/'95 with

increased rates of respiratory illness seen at Great Lakes. But that wasn't worked up as a specific adenovirus outbreak. It was an observation that was made during lapse in supply of the vaccine.

Next slide, please. And it highlights this point. ARD surveillance, acute respiratory disease surveillance, at Great Lakes is not the same as the Army.

Colonel talked about their threshold for ARD, the 1.5 percent in the division that they follow very closely week to week. And they have this admission standard to admit anybody to their ARD ward with fever of 100.5.

We don't have that at Great Lakes. People come in with upper respiratory infections, get treated like people with any other medical sick call thing. And they usually do not get admitted to anything special, any special ward. They may get put sick in quarters, but it's not consistently at a fever threshold that we could specifically track.

Now, ambulatory data systems, the new outpatient surveillance system, will help us track this outpatient morbidity better. But prior to Fall of 1996, this wasn't a specific

thing that we tracked on a week to week basis, like the Army boot camps.

Beginning in November '96, we began doing specific tracking because of the work directed by Naval Health Research Center to do adenovirus surveillance. So we counted total respiratory illnesses seen and febrile respiratory illnesses seen. Our threshold for fever is 100.0. That's just trying to capture a few more cases. There was nothing magic to getting 100.0.

And we noticed, then, with this surveillance in place -- and we're sending these febrile cases cultured to NHRC to test for adenovirus. So that was the incentive behind all that counting of cases. And then febrile cases were getting cultures sent to San Diego.

We saw increased rates of respiratory illness, especially the febrile ARD, in September and October. And we sent over 400 cultures during that time period to San Diego.

Next slide, please. I don't know if you can see the orange, but if you can't, it's crude estimates anyway. But that's total respiratory illness. That's what I can get from outpatient morbidity counting up doctors'

outpatient morbidity, if you will.

And the yellow line, it's febrile respiratory illness, again with that fever of 100.0, counted from the Fall of '96. And probably the *x*-axis isn't labeled. It didn't come out, but it is on your handout. This is October of '96, and this is October of '97. Actually, it starts in September. And right down there is October of '97. So that's where our outbreak is. That little yellow blip is our outbreak.

Again, I already talked about threshold of 1.5 percent of the specific division having ARD. Actually, I wanted to ask the colonel what they do when they hit the threshold. We don't have a threshold at Great Lakes. There's something to do when we hit any particular threshold of febrile illness.

We have specific things we do for strep. And I know that ARD and strep are closely related in Army surveillance. But there's nothing special that happens. The highest we get there is 14 per 1,000, 1.4 percent of the total population, per week in that yellow blip there.

Next slide, please. Now, the overall attack rate, though -- and attack rates are a

little bit difficult because our training is very, very integrated.

The space is very small. The smallest training unit is a division, which is 80 recruits. They're housed in ships which have 12 divisions in them. But they may train with many, many more recruits. So we may have many divisions in the same drill hall at the same time doing things together or big classrooms together.

So there's a lot of mixing of recruits in spaces that are generally indoor spaces. But if I look at a cohort of recruits that came on board in the end of August and call them sort of a training cohort, they came on at the same time, the highest attack rate I could see in such a group would be about five percent.

Now, we have 89, -- and that's for all ARD, all febrile respiratory illness -- 89 culture-confirmed cases of adenovirus illness from that time period. And we expect more as more cultures are being done. This is a lot of work for San Diego that they have been given, and we expect more positives as they keep turning them out.

Of the ones that are serotyped so far, two-thirds were serotyped seven and one-third was

serotyped three. I don't remember Colonel Sanchez saying it, but I believe all of theirs were serotyped four adenovirus. That's kind of interesting. We really did not see a four in the whole group here.

Next slide, please. Now, what did this look like? Again, this looks like a lot what Fort Jackson talked about, although we saw a lot more of the chief complaints on the initial visit as nasal congestion, stuffiness, or rhinorrhea, almost 100 percent. It was 96 percent of them. Sore throat was the second most common and cough up there.

We actually, interestingly enough, saw gastrointestinal symptoms as part of the presenting illness, rarely the chief complaint, but part of the presenting illness, in almost 50 percent of those cases. And that usually was nausea or vomiting.

Now, when you look at that picture of disease, it looks like a cold. But what makes this worse, what makes it difficult is that also in the chief complaint were fever and chills very often.

Now, remember, my case definition includes fever of 100.5. So 100 percent have

fever, but their mean oral temperatures were 102, which was pretty impressive to us. And we had fevers as high as 105.4. These were some pretty high temperatures.

They're very sick-looking kids with a mean duration of illness of 10 days, ranging up to 21 days. And some of them would self-report even more, with 21 days that we could document medically that felt like the length of their illness and lost time from training as 3 days. We call that sick in quarters, or SIQ. It would be the equivalent to the stay in the ARD ward for the Army.

But when we hospitalize them, bring them all the way across the base to the main military treatment facility, that's when they're really sick. And we hospitalized two of those cases. They were each hospitalized for seven days with long convalescence after that.

Those were really sick kids. One of them was the one with the 105.4 fever, very frustrating medically for the docs and other health care providers at Great Lakes. These were kids that looked real sick that weren't getting better, despite what we threw at them except by tincture of time, if you will.

Next slide, please. The culture-confirmed cases originally diagnosed, as you can imagine, just with those presenting symptoms. Many of our docs labeled this "viral syndrome," quite appropriately, but a lot of sinusitis and bronchitis diagnosed there and pharyngitis, not quite as much universally seen as those ugly tonsils that you saw in the Fort Jackson picture. But we did hear about ugly tonsils. And those would be like the pharyngitis diagnosis.

And over half were given antibiotics at some point during their illness. If this happened in the civilian world, I would expect that to be closer to 100 percent. We have a lot of incentives not to give antibiotics over on the recruit side, believe it or not. And they really try not to treat viral infections with antibiotics. But half of these kids were given antibiotics, in general because of the fever.

Now, no difference was seen in the characterization of Serotype 7 and Serotype 3 for the data I've got. I was interested particularly in a couple cases that the one-third that grew three so far, Serotype 3, to see if they were just as sick.

That guy who was hospitalized with the 105.4 and was super sick had Serotype 3 adenovirus infection. And there really was no overall difference between the 3's and 7's.

Next slide, please. The onset of illness, again, this mirrors Fort Jackson. The average onset was 40 days after being on board with a range of 2 weeks up to over 2 months on board before somebody presented with illness.

These are all recruits, by the way. I have no AIT or follow-on training people in here. People are sometimes at Great Lakes for longer than two months for being set back in training. That happens, unfortunately, not too infrequently, but in general these illnesses occurred after, well after, coming on board.

We did a demographic comparison between the cases and their recruit peers during the time period. There was no difference in age -- the mean age is 19 years, just like all recruits -- or gender -- about 80 percent are male and 20 percent female, just like the cohort of recruits -- or race, which is about 60 percent Caucasian and 25 percent African-American, or smoking history prior to enlistment -- nobody's smoking in boot camp, of course, but we had

smoking history prior to enlistment -- or home of record, where they came from. There was really a good cross-section of all over the United States that these recruits came from. In general, it was where they came to that got them.

Next, please, slide, please. So what did we do? In general, we reintroduced the oral vaccine on 16 October, the first day we possibly could. And then we made house calls out into our division space, our ships, if you will, and played catchup with recruits who were still in their first half of training.

So we covered a lot of the base with adenovirus vaccine as soon as we could, rather than just putting it in in in-processing. And I think that that did have a positive effect on bringing down that outbreak during that defined period.

We did reemphasize the hygiene and hand-washing, something I presented last time called Operation Stop Cough. Operation Stop Cough has been active at Great Lakes.

We have soap in all of our barracks now. We have training on hygiene and hand-washing. There are no case and control groups, though, here. This gets implemented as

well as the drill instructors choose to implement it. It's still a fairly strong push at Great Lakes.

We did find that when we went out to reemphasize it specifically after the adenovirus incident, that we found a lot of people lagging in keeping up with good hygiene and hand-washing. So I can't tell you that that specifically helped, but we did do a lot of reemphasis and some improvement certainly in overall disease rate.

We had decreased crowding at boot camp. We're very attuned to this crowding issue. And we didn't do any environmental sampling, as was nicely done at Jackson, but what happened to us is an artifact of what happens in boot camp in the fall.

We peaked out at a population of 13,500 on board on 1 October, which was our peak for the year. And, frankly, that's really darned crowded. That is about as packed in as we can get and still feed and clothe and take care of everybody. That is really crowded.

On 1 December, just recently, we are down to about 2,300, which is a much more comfortable population for Great Lakes. We don't

have the option to open windows very often. Beginning in September, we start to get to really cold temperatures there. So we didn't do any division space looks. I can tell you, yes, our CO_2 levels are probably pretty darned high when we're packed in really tight there.

Another point I wanted to leave you with is if we had a subsequent strep/pharyngitis outbreak in November, it seemed to follow right on the tail of the adenovirus outbreak. So we had a provider seeing sick kids with fevers and nasal congestion in this picture that I painted for you.

Then right as that overall rate of sick call started to go down, we started to see a lot more throats that just looked clinically like strep. And we culture every sore throat. We were culturing all of these guys with throats. We're not finding strep during that period. And right afterwards, we just found lots and lots of strep.

We had stopped doing bicillin prophylaxis when the strep rate become nice and low this past summer. And we had to reinstitute it when the strep break jumped up in the first week of November.

Next slide, please. Now, this is one thing we track well at Great Lakes, which is the strep rate. We throat culture every recruit. The *y*-axis here is a lot more blown-up than you would have seen from our ARD graph in the beginning. But you can see that in November, the strep rate started to take off.

We did lots of bicillin and lots of bicillin catchup. And that even this past week has come down even farther. So our strep rate really came down nicely after reinstitution of bicillin.

We hate doing massive bicillin, of course, as most people in public health do, but it works. And it really did bring our strep rate down.

I don't think that that's a coincidence, by the way, that strep followed closely on the tails of adenovirus, an interesting observation for us that you might have expected with all the sort of coughing, hacking, and nasal dripping that goes along with adenovirus to think that we could be in a nice situation to transmit another pathogen very well following on such an outbreak.

That's all I've got. Any questions?

MODERATOR FLETCHER: Thank you.

Put the lights on. And any comments or questions?

DR. REINGOLD: For Colonel Sanchez, I think you had six barracks, six units where you had an introduction, a culture-confirmed introduction, of adenovirus and the three you had and a cluster of three you didn't.

I was wondering in terms of your attempt to discern what environmental factors might be important whether you tried to vary them with the three where you had a confirmed introduction and did get outbreaks and the three where you didn't. It seems to me that might be a fruitful approach, rather than --

COL SANCHEZ: We're going to have to look at that. I'm going to have to look at it.

MODERATOR FLETCHER: Other questions/comments? Yes, sir?

MAJ NANG: Major Roberto Nang, U.S. Army Center for Health Promotion and Preventive Medicine. This question is for Lieutenant Commander Ryan.

Ma'am, I was just curious. The Operation Stop Cough, that was already in effect prior to the outbreak at Great Lakes?

LCDR RYAN: Yes, it was. Actually, Operation Stop Cough began just over a year ago. And it was actually our response to what we thought would be an impending crisis with respiratory disease as you lose adenovirus vaccine.

MODERATOR FLETCHER: What was that, please?

LCDR RYAN: Operation Stop Cough is our line-type term to promote hand-washing among the recruits. And it was a big change for them. We have a lot more hand-washing than we have had before.

Yes, sir?

MODERATOR FLETCHER: Colonel O'Donnell?

COL O'DONNELL: When you talked about strep follow-on to the adenovirus, you made the statement sort of on a population basis, that the population got set up for a follow-on strep, those things going up.

I was just wondering if you know and are willing to speculate whether or not that's true for individuals. Having had adenovirus, as an individual, you become more susceptible to strep disease.

LCDR RYAN: Thank you. Colonel DeFraites asked me the same question. Those strep cases were not in the adeno population. People who had adenovirus were no more likely to get strep than the rest of the cohort. So actually the strep incidence and the people who had adenovirus were slightly lower than the strep incidence in their peers from the same training period.

DR. JACKSON: It sounded like three of the six recruits that were adenovirus-positive at Fort Jackson then washed out at the same time. I was interested in the issue of when you arrive sick and you're suddenly thrown into an extremely stressful environment physically and every other way. That's a real setup for failure. What's your thought on that?

COL SANCHEZ: Well, I think what you're seeing there -- and I don't want an overemphasis on our discussion on this point. I must say he emphasized those same points.

The point is you have amplification of this virus. So it will take two incubation periods, maybe three for them to hit one-half percent, two percent, three percent of the company.

Now, remember, they train by platoons, as I mentioned to you. There are four platoons per company. So even within those companies, if I broke that down, I'm sure I could find specific platoons at even higher rates. Be that as it may. So I think what you're seeing is a function of amplification of the virus.

Now, another point that you may not know is on week seven, these individuals go into the field. So it ceases to become a crowded environment where they sleep indoors. And they suddenly are trusted for four to five days into the field scenario, where they sleep in their own tents with their buddies on twos, twos and twos. Okay? So that serves to break some of the chain of transmission, too, even before they actually graduate on weeks seven and eight.

DR. JACKSON: I guess my point is that there's a double incentive not to have groups who were getting sick. A) they're at entire risk of wiping out, maybe. I'm just making this up listening to you. But B) they're also seating the larger group.

LCDR RYAN: I would agree. I heard that in your question, too, which is not just: Is this lost time for training, like three days

sick in quarters, but are these guys dropping out? Are we losing recruits because they're sick in training?

To be honest, I can't tell you that any of these who have attrited dropped out of training, but that's a huge issue in DoD, attrition, because it's just such a waste for us to train somebody to some form and then lose them altogether. It's time to quit.

It is a big motivational problem when people have sickness for any reason during week one. And it has been proposed before that more sick call visits correlate with more attrition. It's hard to separate out whether that's just becoming demotivated because you have respiratory illness or don't miss a call because there's other stuff on that you need to try for.

But that is a big concern. We lose a lot of motivation recruits when we have somebody sick, and that does affect attrition.

LTC DeFRAITES: This is Bob DeFraites.

I thought I heard -- Tony, did you say that those three guys who had adenovirus who left never got out of the reception?

COL SANCHEZ: That is true.

LTC DeFRAITES: They didn't even start

training? They left when the time came --

COL SANCHEZ: There were six others. There were a total of nine. Three never made it to the basic training. The other six did, three of which merely preceded or started right at the time that their prospective companies started.

MODERATOR FLETCHER: Dr. Poland, comments or questions?

DR. POLAND: Is there anything from the AFEB that we could do to be helpful, any recommendations?

LCDR RYAN: It's difficult. We need to maybe talk about it in a subgroup. We really are anxious and scared about what happens in the absence of vaccine. I don't know the AFEB's role to give us the vaccine, but we are concerned, sure, if we don't get shelf life extended or if we just don't have vaccine.

MODERATOR FLETCHER: Now, you're sure of that until August of '98, I believe you said?

LCDR RYAN: We're covered until August of '98. That's right.

MODERATOR FLETCHER: '98?

LCDR RYAN: That's right.

COL SANCHEZ: I have a more basic concern if you're doing research and a capability

concern, if you will. There's no more right now. In fact, adenovirus or respiratory diseases are not identified as a separate research area.

This goes beyond us here in this room, but there's no support right now for doing all of this laboratory work of this kind. It has to come about out of our operational funding. This is still running in our operational money because it relates to laboratory type, developing new tests and so forth.

So I would suggest to you if you could come up with a strong recommendation for the medical research community to come up with those funds.

MODERATOR FLETCHER: Other questions, comments?

LTC RUBERTONE: One more question.

MODERATOR FLETCHER: Yes?

LTC RUBERTONE: You had alluded to a question of what happens when we cross the threshold at the Army recruit camps. One of the things that happens, in addition to the operation investigation, is starting bicillin. I was wondering at the training camp for the Navy, what the threshold is of starting bicillin. You started it when I think there were about 6 cases

per 1,000. So it would be .06 percent.

We have a very hard time taking people off bicillin, especially the commanders, who receive a great benefit being on bicillin because it not only reduces strep but I think it's been publicly shown that it reduces all rates of ARD admissions, not only strep-related ones.

LCDR RYAN: Right. That's what I was asking about, too. I know your ARD and strep are closely linked. And it's prompted by some pure strep that gets some bicillin.

And it's 10 per 1,000 per week, or one percent per week, in the whole boot camp, one percent per week in late training recruits, recruits after 32 days on board when we assume their initial bicillin is no longer covering them. So we follow them. Actually, I didn't show that detail on graph, but we follow both rates: total recruits and second-half trainees.

We didn't actually meet that rate in November to restart bicillin or on such a sharp upward trend. We just said, "Let's do it because it's going to take us a while to catch up." We were headed there real fast.

But you're right. Once we started, everybody loves it when they see the rates come

down. And, like I said, from a public health perspective, we sort of hate the idea, but I've grown to love bicillin, too. It's really a tough position to be in, but you love bicillin when you see what it does for you.

MODERATOR FLETCHER: Dr. Stevens?

DR. STEVENS: Have you had any strep complications with rheumatic fever?

LCDR RYAN: Actually, we've had one case of strep-related toxic shock syndrome in a young female recruit, who subsequently went into ARDS. She's expected to make a full recovery, but she is still in an acute care hospital setting. And that was a complication of strep throat.

We saw some peritonsil abscesses, which is not unusual, with strep, but we had seen so rheumatic fever, no strep with nephritis, and no necrotizing fascitis with the recent strep outbreak.

MODERATOR FLETCHER: Other questions, comments? Dr. Allen?

DR. ALLEN: Are you doing any surveillance at all for penicillin-resistant strains?

LCDR RYAN: Yes. We were supposed to

take a minimum of one isolate per month to do antibiotic resistance. Actually, Naval Health Research Center is going to begin to support us even more with that on January 1st, taking a whole bunch of our isolates for antibiotic resistance, probably as much as 50 percent of our throat isolates, for strep antibiotic resistance. So we're very concerned about that issue.

DR. ALLEN: Any results so far?

LCDR RYAN: We've never seen antibiotic-resistant strep yet, no.

CAPT GRAY: Greg Gray from the Naval Health Research Center.

A number of years ago, we did this more routinely in the San Diego area, and even for erythromycin. There's never been penicillin resistance. There's been a debatable issue of penicillin tolerance.

With the pneumococcal problem, we're envisioning using our multi-center surveillance to look for cross-tie services for both pathogens for antibiotic resistance.

I think we're looking at five different E test strips, including cephalosporin. So we'll have some answers for you in a year or so, but the word I have is there has really not

been an erythromycin problem for strep pyogenes.

And the prevalence of penicillin resistance among the strep pneumonia has gone real high.

MODERATOR FLETCHER: Other comments?

(No response.)

MODERATOR FLETCHER: Thank you very much.

(Applause.)

EXECUTIVE SECRETARY FOGELMAN: We will adjourn for lunch now. Be back at 1:15. Before you leave, again I'd like to remind you that we have about 50 seats reserved over at the Malone House. So for the Board members and consultants and others who would like to go there, you'll have a place to eat. And we'll have a short talk by Dr. Fletcher before Colonel Gardner's presentation this afternoon.

We have about 20 people signed up to go to dinner tonight. Before we actually adjourn for the subcommittees, we'll have to make some decisions. And I'll need to know from the Board members and consultants who are going how many, if any, have cars so we can figure out transportation. So we'll see you back at 1:15.

MODERATOR FLETCHER: 1:15.

(Whereupon, a luncheon recess was taken at 1215 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1325 p.m.)

GLOBAL DISEASE BURDENS

MODERATOR FLETCHER: What I'd like to do for the first few minutes, five minutes or so, is to sort of issue an alert, something that has been going on in my particular area of interest, in cardiovascular disease and worldwide, that I think is worth mentioning for the sake of what we do in global activity through the military deployments and so forth. So the first part of this message is locally.

There are 5.4 billion people in this country. One-twentieth of this group is in America. And if we can focus out a little bit? I'm not sure what's going on here. 5.4 billion people in this world. Did I say "this country"? There may be. You don't know.

So we have one-twentieth of the population in this country and reflecting from the American Heart Association some data we have had just as really the preliminary. In this country every 34 seconds an American dies of cardiovascular disease. This is primarily acute infarction. And that's more than 900,000 deaths annually, more than 42 percent of all deaths

every year.

Again, according to Heart Association data, 70 million people, Americans, have some form of cardiovascular disease. This might include stroke, heart attack, heart disease, high blood pressure, and you can see the breakdown here for that.

We are really doing very well with rheumatic fever, but, I think as reflected in some of our previous discussions today, we still haven't eradicated rheumatic fever.

Stroke is going up probably, as all the others are here. But that is what is happening in the United States. And sort of breaking it down for other diseases, leading causes of deaths in males and females, you can see how it compares with the women, in green, and the men, in yellow/orange.

Of course, cardiovascular disease is number one, but we're dealing with all of the others, as you can see, in a significant fashion. And I think we are making indentations of this.

People are getting older. And we're seeing more and more of this disease. The death rates are down, but the prevalence and the active living people who have this disease are quite

significant still.

Perhaps some of you saw in the newspapers about a year ago, "A new health study predicts shifts in disease threat." This is something that we have been addressing through an international group through the American Heart Association. I think you can see it better as I explained where this comes from.

In 1944, the World Bank was organized in the waning months of World War II as an organization to collect funds from developed countries, from developed countries, such as America, Japan, and others to provide monies to developing countries that we will mention, where we will see this shift in disease prevalence.

Now, the World Bank was asked by the World Health Organization to work with them in developing a group of statistics, which has just been published through the Harvard Press and analyzed by the Harvard School of Public Health, which is a credible institution.

Murray was involved at that at Harvard and Lopez from the World Health Organization. And Jim Chin, of course, spent he just told me five or so years with World Health. And he might want to comment on this.

In '90, the data was collected to project to 2020. And, as some of the authors say, this is somewhat of an egalitarian approach assuming that all developing countries have equality in politics and social issues.

The average age of expectancy from men in this particular study was 80, and women was 82. And this is round-the-world statistics, absolutely the way this data is projected and based in a way that not being an epidemiologist, I would not want to comment on how it was done.

But the impact of this and just being utilized in health around the country now, particularly International Heart Association activities, is very significant. So we can see the collaboration by the World Health Organization, the World Bank, the Harvard Press, and the Harvard School of Public Health.

There's a large number of volumes on this, but I think I just want to show you some of the data they have looked at from 1990 to 2020. The projected trends in death by broad groups in developing regions have changed, as you might see, from the decrease in communicable diseases, as you see here right here, decrease in 1990 projected to 2020, infectious diseases, going up,

ischemic diseases of the heart.

These were related to heart attack, high blood pressure, and heart failure from that, also various types of heart disease related to risk factors of life, lifestyle, decreasing, as I said, communicable diseases but increasing slightly deaths from accidents, primarily motor vehicular accidents. This is the trend up to 2020.

Now, breaking this down sort of, of the top five, this is 1990, what happened in the relative instance of these problems. This is what is predicted in 2020. You can see ischemic heart disease in 1990 predicted to be the number one.

So all the tobacco issues and so forth. This will show you a trend. Tobacco is going international. You're having this country but not very well internationally.

Number two is unipolar major depression, surprisingly going up from number four to number two. Around the world, that will be coming.

Number three, as I mentioned, road-tracking accidents, coming from number nine to number three: vehicles, fast cars, the fast

track.

Number four, cerebrovascular disease, another type of disease of lifestyle, going from number six to number four.

And then related, if you like, to tobacco, environment, air, whatever is going to happen, as they predict in 2020, respiratory diseases going from number 12 to number 5. And you can see the trends of those.

So this is what we are faced with based on this study after the millennium in 2020. A few of us will be a little bit older at that point. I think most of us will be around probably. A lot of you will be in your prime by then. We'll be here. We'll be watching this. Some of us will be working part-time by 2020, but we'll be around.

Last, but not least, I think, one way they looked at this -- and, again, it is a little while -- disability-adjusted life years for the way that many experts are looking at life expectancy.

This takes into account two things. Your premature death before that age of 80 is the reason I mentioned that, which is the projected age of women and 82 men and also the disability

within that life span.

This includes disability and death as premature. And going up, as you can see, related to tobacco, the trend up to 2020: diarrhea, for example, coming down; HIV going up, sort of plateauing, in 2020.

So this is all I wanted to say. I just wanted to bring this up because I think this deals with what we're doing in the military a lot. And people are international nowadays, not just our military personnel, but many of us.

So this is something I think we're trying to make attention to in the Heart Association. And, just for your information, I felt we could consider this an alert because this is what the data is.

Now, Jim Chin here might want to comment on this -- he's been involved in the WHO -- or anybody else. This is just something that we are trying to address through the international component of the American Heart Association.

DR. CHIN: I know Alan Lopez very well. He's a very good demographer. And I think those people who are familiar with demography know that they have to use their own models and

they have to make a lot of assumptions.

Broadly speaking, I think a lot of what they predict will go hand in hand with basically controlled communicable disease in general: aging, what to expect, what's happening with tobacco. So I think there are no major surprises. I think if we look out 20-30 years, that's basically the general trend.

MODERATOR FLETCHER: What we have seen in countries talking to people who are trying to control blood cholesterol -- there are many cholesterol drugs. We have Merck here today, and they make some of this.

People in the foreign countries, they're not using drugs more than a month sometimes. Patients take them and say, "Geez, my cholesterol is down." The doctor says, "Well, you've probably taken it long enough," and they don't take it. These are lifelong drugs.

I would guess there are ten million people in this country on statin drugs for cholesterol. I would guess ten million, and it's probably more.

But outside of this country, in South America and Europe, even in Europe, we have a very good health practice. That's what we do.

That is a major, major risk for coronary artery disease. So these are real true facts that I think we're going to have to face. It's slowly, though. 2020, that's is a long time.

Thank you very much.

DR. LaROSA: Jim?

MODERATOR FLETCHER: Yes?

DR. LaROSA: I thought heart disease -- I may have misread it, but I thought it was the leading cause of death worldwide now.

MODERATOR FLETCHER: I can't say that for sure. With all the countries that still have communicable disease, I don't know. You may learn that. It's near the top.

DR. LaROSA: Right.

MODERATOR FLETCHER: Jim, would you comment on that? There's still a lot of communicable diseases.

EXECUTIVE SECRETARY FOGELMAN: Dr. Waldman?

DR. WALDMAN: The data is showing us, as Gerry showed, it's a question of premature death and disability essentially. So as long as young childhood deaths are important in that array of diseases, they're going to rank higher. So it's not a question of the numbers of

absolute deaths, but more a question of the year's potential ahead. A combination of aging with control of early childhood deaths will change the ranking.

MODERATOR FLETCHER: Somebody called it quality-adjusted life years, which, again, I don't know how to analyze these things, but those are ways people look at it: disability-adjusted life years and quality-adjusted life years.

Thank you very much. Now we'll go to Dr. Gardner? Our next presentation --

(Applause.)

EXECUTIVE SECRETARY FOGELMAN: Okay. Our next speaker will be Dr. Colonel John Gardner, who is Professor of Preventive Medicine, Biometrics at the Uniformed Services University of the Health Sciences. He's talked to us before. Today he will be talking to us about a proposal for a DoD mortality registry.

Before he gets started, is Dr. Sanchez here or anyone from CHPPM?

PROPOSAL FOR A DoD MORTALITY REGISTRY

COL GARDNER: I'll talk today about the concept of a DoD active-duty mortality registry. I've been interested to watch the proceedings this morning, where we spent a large

amount of time on surveillance. And not once was that brought up.

I really consider that the first step of a surveillance system is timely and accurate reporting of disease-specific mortalities and mortality rates.

Why do we want to focus on deaths? I think there are a lot of good reasons. First of all, death is an objective endpoint. It's something that's not difficult to determine whether or not it's happened. Getting into what the cause of death is is much more difficult. It represents the most serious aspect of those. It's high visibility.

There's a lot of interest in the press. Often it's not. Most of them are congressional inquiries when we have deaths, particularly in recruits.

There's often litigation. It can be expensive. And there are policy implications. Often we see a single death create a whole change in the way we do business. And that phenomenon is one that has been quite interesting.

We're working now with a death in a recruit with sickle cell trait at Great Lakes last winter, which is changing their whole

concept of how they approach dealing with sickle cell trait issues.

We watched the same thing happen to the Air Force a couple of years ago. And, despite thorough study and recommendations, the policy is driven by the death, not by the pattern of deaths.

And in terms of surveillance, deaths represent the tip of the iceberg. It really doesn't make a lot of sense to me to spend tremendous efforts looking under the water when you don't know what's on top of the water first.

I think that in terms of surveillance, deaths may not be very common, but because they're not so common and they represent the most serious aspect of illness, we really need to understand them the best. So that's really the purpose of DoD death registry.

Well, what are we doing now? Well, in the civilian sector, we have the National Center for Health Statistics. We have death certification and death certificates on every death with some cause-of-death information. We have ICD-9 coding and a lot of data collected related to deaths. Even in that system, we know there are lots of errors. I worked for many

years with cancer registries. We looked at cancer registry diagnoses compared to death certificate diagnoses. Even in cancer, you have a 20 percent error rate on the death certificate.

What are we doing in the military? Well, in the military, we have the DD-1300, which is the military death certificate. Sometimes you get a civilian death certificate also, but that's not really part of the military process. And the DD-1300 is the official item.

That has minimal cause information on it. It's not coded. And it's not even catalogued by cause. We have the world-wide casualty system, which is run by the Washington headquarters service and Defense or DIOR, department information operations reports. And they collect the DD-1300 information from every casualty center from each of the Services.

The casualty centers collect all the deaths from those Services. And I think they do a really good job at what they're trying to do, but they really have a mortician's philosophy. They're interested in: proper disposal of the body, proper coordination of benefits for the family. And they have essentially no medical interest.

In fact, we used to use data tapes from DIOR to look at military deaths. And we found they had deaths categorized by cause in about 50 categories, nowhere near the detail you see in ICD-9.

In 1990, they stopped that. Now those deaths are collected in six categories: accident, disease, homicide, suicide, hostile action, and other. And, really, the sum of death registration in the military is represented by what you saw Jim Helmkamp do.

And if you look at this, you realize it's in categories of: accident, illness, homicide, and suicide. And that's because he got the data from DIOR because that's the only place that has them all.

In fact, he had to go to CDC, to NIOSH to do the study. It was while he was detailed to NIOSH that he was able to get time and resources to study deaths in the military.

How should deaths be collected? How should the data on deaths be collected? That's my focus for discussion. Assuming everyone will accept the fact that it's important we ought to do it, there really is no systematic way except through the DIOR system and the reportable

disease system that's being done in the military.

While my proposal is that we collect in real time -- and by "real time," it's not daily. You really can't collect what you need in terms of deaths on a daily basis, but then if you collect all of the information you need, it takes two or three months at least to collect all the information you need because most of these are investigated extensively. And those investigations take several months to do.

But you would collect in roughly real time all active-duty deaths in all Services. Jim Helmkamp had an average of 1,900 deaths per year in his data, which went through 1993. By 1993, due primarily to downsizing, we're down to about 1,200 deaths per year. So that's 100 a month.

What you need to collect -- and I'll go into more reasons for that in a few minutes -- is the death certificate. And preferably a civilian death certificate has more useful information on it: the medical record, at least the acute record of the event of death, but the other records might be also useful, the local autopsy, the AFAP consult autopsy, which occurs quite frequently, and toxicology studies, which tell you whether or not there's alcohol or drugs

involved.

And what we found is most critical is the eyewitness accounts. You get the eyewitness accounts from usually the legal investigation that accompanies most deaths. In addition to that, you need to get population data so you can calculate rates and not just deal with numerators.

So my proposal is that we collect the critical information, that we mainly review that to maintain a medical surveillance database, that that database be shared with DMSS and other people who could use it and provide reports and so on so that we can really utilize these deaths in prevention.

The rest of the time I really would like to focus on the amount of detail you need because without detailed medical information on each death, you really don't have the opportunity to know: number one, whether the data you're collecting is accurate; number two, the subtleties of the disease that you're trying to look at; or, number three, to determine any effective intervention.

It doesn't do much good for emerging infectious disease surveillance to know that

there was a Navy sailor who died in Bethesda Naval Hospital from pneumonia, which is all you'll find on a death certificate.

You need to know what organism he had. You need to know whether it was antibiotic-resistant or not. And, most importantly, you need to know where he got infected.

The fact that he ended up at Naval Hospital and came from Africa or somewhere else won't be reflected on the death certificate or the autopsy usually. That you find only from perhaps the medical record and the eyewitness accounts.

So what I'd like to do for another five or ten minutes or so is just review what we've learned about recruit deaths and our studies of exercise-related deaths and military recruit training. This goes back. This is primarily Dr. John Kark, who started these studies back in about 1980, to review that.

I'm going to focus primarily on the recruit deaths from 1977 to '81 because those are the ones which were most thoroughly studied just to give you an illustration of what you can learn from accurate death reporting and what some of

the pitfalls are that you need to look for.

The recruits in the five years 1977 to '81, there were two million recruits trained in all four Services. As you know, recruits are medically screened before they arrive.

They're 88 percent male, 96 percent in the 17 to 25-year age range, 22 percent black. And they go through a rapid physical conditioning program in recruit training that focuses for physical condition primarily or largely on middle distance runs, one to three-mile and some five-mile runs, as well as their marches and so on.

The way the data are collected is Dr. Kark visited personally every basic training site and at that site went to the Hepatology Department, collected all the autopsy records; and went to the hospital patient administration departments and collected all of their death records; and, in fact, went through every autopsy of any individual under 35: first, to identify whether they're active duty and, second, to identify whether they're a recruit; and then through collecting all of those, brought those back for study.

He went to the Armed Forces Institute

of Pathology to collect all the deaths through that system, also got the toxicology records, went to the Casualty Affair Offices for each Service to identify all of the deaths that occurred in recruits through their system, went to the DMDC database to identify both deaths and get population data, and went to the JAG Department, the Legal Department of each Service, to get their copies of their legal investigation on each death -- that's where most of the eyewitness accounts are contained, and most of those legal investigations have page after page of statements from eyewitnesses -- and then subsequent to that went back to AFIP and collaborated primarily with the cardiovascular pathologists there but also with others as needed to review each case in detail and to pull the file tissue specimens and reevaluate and reexamine those to determine what the true cause of death was or the best we could get cause of death was in each case. And so they rereviewed the tissue on nearly all of these cases.

Now, just to put this in context, let's look at what kills people in the United States. In this age, 15 to 24-year age range, is the same now in the first year for many men and

women.

Actually, it's homicide, suicide, cancer, and heart disease. Just this year, it switched. This year is '95. That's the last year of data available. Suicide and cancer just switched places in women. So they're now both the same. So this is what you expect to see, we expect to see in recruits also.

In 2 million recruits in this 5-year period, we have 87 deaths during recruit training. Recruit training lasts from six to ten weeks depending on which Service you're in. I think the Navy and the Army are eight weeks and the Air Force is six. The Marine Corps at that time was ten.

So 87 deaths out of 2 million trainees. About half of them were exercise-related deaths and about a quarter each violent deaths and non-exercise-related deaths.

And if you look at just the violent deaths and try to convert that to an annualized rate to compare it to U.S. data, basically we took the average of 8 weeks and multiplied each of the deaths by the death, the rate per 1,000 accessions by 6 and a half to get rate per 100,000 person-years.

You see that the rates of violent deaths are way below what we see in the civilian sector. And the others -- we couldn't really categorize those separately -- come out a little below what you see in the civilian sector.

Again go to the -- go ahead.

DR. HAYWOOD: Are these age-matched?

COL GARDNER: This is the recruit population compared to 15 to 24-year-old civilian population. So they're not quite age-matched but as close as we could get.

Here are the violent deaths, 13 suicides, 4 homicides, 4 accidents. Even though you see a lot of suicides there, still those rates are well below the civilian rates. And we do really well in violent deaths. During recruit training, it's pretty tough. It's a rigid environment. So the accident, homicide, and suicide rates are all very, very low.

Here are the non-exercise-related deaths: meningococcal, pneumonia, and epiglottitis, systemic disease, and then sudden death at rest. Those are presumed heart disease. Actually, two of those three had artery anomalies, anomalous coronary arteries or at least anatomic coronary heart defects. The

systemic disease, two were sickle cell disease, others with serious systemic disease that was missed or concealed during recruiting.

Then you go to the exercise-related deaths. Here you see there are 41 exercise-related deaths. Thirteen of them had a preexisting condition. Most of those are cardiovascular, heart problems, anomalous coronary arteries, valvular stenosis, hypertrophic cardiomyopathy, myocarditis, and a couple of ruptured bari-aneurysms.

Then you have those without the preexisting condition. And of those, 14 were unexplained sudden deaths, presumably cardiac arrhythmias. And the other 14 were exertional heat illness, heat stroke, or severe rhabdomyolysis.

Dr. Kark is a hematologist and was doing all of this because of sickle cell trait issues. Just to emphasize that you see in this group of no preexisting condition, 13 of the 28 had sickle cell trait.

So that's nearly half of those unexplained sudden deaths that occurred in individuals with sickle cell trait when a sickle cell trait in the population is 8 percent of

blacks, which is 20 percent. So you're down well below two percent of the population having sickle cell trait resulting in nearly half the deaths.

And that's the 30-fold excess risk for exercise-related death, unexplained exercise-related death, you see in those with sickle cell trait that he published back in 1988-87.

DR. HAYWOOD: The events were racially skewed. Is that right?

COL GARDNER: Well, not racially. Sickle cell trait, sickle cell trait-skewed. And there were 14 with sickle cell trait. Thirteen of them were unexplained, by "unexplained," meaning no preexisting conditions. Of those, about half were heat illness. About half were presumably cardiac. And then there's one who had a cardiac lesion that was considered cause of death.

I'll just make one comment on that because that's not my topic today. In some studies, we have shown that the risks for exertional heat illness in those with sickle cell trait and those without is about the same. The difference is not in the risk for heat illness. There were differences in risk for death usually

related to heat illness or often related to heat illness.

How does this compare with what's in the literature? Well, if you look at the, of course, medical literature, exercise-related deaths, they will tell you that 85 percent of those deaths are explained by cardiac lesions and a few with non-cardiac, like the subarachnoid hemorrhages, very few with exertional heat illness, and then the unexplained group.

Now, that should be 34 percent over here military and 12 percent who hadn't been over here under literature; whereas, in our population, we see only about a third in the explained category and about a third in heat illness category, about a third in the unexplained sudden death category.

Why that difference? Most of the literature, studies you see in the literature are collections from primarily cardiovascular pathologists. And there is selection bias in the way these patients are referred to them.

Most, some but most -- some are not. Some are population-based, but most are not population-based. And they represent patients referred to by pathology subspecialists.

In fact, there is bias in the way that they're defined. These studies are usually defined as sudden death occurring within an hour. Well, most heat illness death, rhabdomyolysis death gets fatally ill within an hour, but they don't die for 6, 12, or 24-36 hours, sometimes 2 or 3 days later. So that selectively excludes the heat illness deaths.

And then there is often an unclear definition of sudden death. And there is often a reliance on death certificate diagnosis or autopsy diagnosis. And I'll show you right now that that reliance is not good enough.

What we found in review of these deaths was that 77 percent of the death certificates had major errors in cause of death. And, in fact, the local autopsies, 44 percent, 45 percent, contained major errors. And even the routine AFIP consultation had major errors.

I could give you numerous examples. In fact, the most common major error is attributing annual changes to cause of death: aspiration, sickle cell crisis.

If you see sickling, sickling is an annual change, a postmortem event in particularly an individual with sickle cell trait -- and it's

often misinterpreted to be the cause of death -- and drowning.

Now, drowning is a classic. We had two in this series. And we have several others where the recruit jumped in the pool, swam all the way across, swam all the way back, got ten feet from the end, and then suddenly stopped and sunk to the bottom. They fished him out but couldn't resuscitate him.

The death certificate says drowning. The local autopsy says, "Cause of death: drowning." Down to the heart, it mentions myocardial infiltrate.

The AFIP consult says, "Cause of death: drowning." Under "The Heart," it mentions myocardial infiltrate and myocarditis. In fact, you realize that is a cardiac death, not a death due to drowning.

We have in the Navy last year the same situation. It was originally called a sickle cell crisis. The cause of death was sickle cell crisis. Upon review and discussion, they have now changed that to be an unexplained sudden death, presumed cardiac arrhythmia.

All I'm showing you is the 20 major errors in the local autopsy diagnoses. Ten of

those were due to annual changes. Four more were due to over-interpretation of the cardiac histology, where the cardiovascular subspecialists, cardiopathology subspecialists felt that these were benign conditions that could not explain the deaths. Three more were under interpretation; that is, they missed things that they considered were the cause of death and then a few others, like the one with epiglottitis was called pulmonary hypertension, and so on.

I think that's the end of the slides. Just one more. Here we have taken deaths through 1990, exercise-related deaths through 1990, just to show there's roughly the same pattern. Those are not as well-studied, but a similar pattern in terms of the findings.

The point here is that in order to understand what happened, you really have to have more information than what's on the death certificate or even what's on the autopsy. And you don't find that information on any computerized database. You need to really go out and get that information yourself.

Any questions?

MODERATOR FLETCHER: Thank you very much.

Any questions or comments? I applaud your efforts. In the civilian world, still many times I see on death certificates cause of death in ventricular populations cardiac arrests. That's the safest thing to say because that's going to happen to everybody. And, really, we still see that a lot. People don't want to say why this person dies.

Dr. Reingold?

DR. REINGOLD: Yes. I have two questions. One is what proportion of the deaths in the military undergo autopsy.

COL GARDNER: For recruits, nearly all. In fact, the exercise-related deaths --

DR. REINGOLD: But not in recruits. In terms of what you're planning to do in the future, you're going to have all active military. So do you have a sense of what --

COL GARDNER: It varies because it depends on whether they died on base or off base or who has jurisdiction and so on. It's higher than the civilian sector is. Let me put it that way.

DR. REINGOLD: My other question is, I mean, as you pointed out, this would not be adequate to simply get the best available data.

What you really want is to make sure that everyone who dies has an autopsy and that all the specimens or some of the specimens are read by an expert team of pathologists in one location so you're not depending on --

COL GARDNER: Well, the exercise-related deaths are probably the most difficult and really do require that. There are other types of deaths that may not be so critical. For example, 60 to 70 percent of deaths are motor vehicle accidents. Perhaps not all of those need that level of investigation.

MODERATOR FLETCHER: Dr. Baker?

PROFESSOR BAKER: Given that maybe 80 percent of all the deaths are injury-related, even more when you include suicide and homicide, and that most of these would in the civilian world be investigated to some extent by medical examiners or coroners with some investigation, some by standards, is there some way of getting that information routinely into the military records?

DR. PERROTTA: That's the proposal. We're not proposing to go out and do all these special studies on every death. We're simply proposing to collect all of the available

information on every death so it then can be reviewed, looked at. And in special cases and special disease types and circumstances, then it might be worth the extra effort to go get extra information that's not routinely collected.

PROFESSOR BAKER: Is there anything the AFEB can do to make that happen? I think it's terribly important.

PARTICIPANT: That's what we're going to talk about in committee meeting.

EXECUTIVE SECRETARY FOGELMAN: Right. We're going to have a discussion in committee on this.

PARTICIPANT: We're going to ask John to have a little more detail.

EXECUTIVE SECRETARY FOGELMAN: I think in the interest of time, if we could, unless you have some real important questions, hold them until the subcommittee meeting or maybe ask Dr. Perrotta offline, I think we ought to start to break out.

MODERATOR FLETCHER: Anybody else? Dr. Haywood has a --

EXECUTIVE SECRETARY FOGELMAN: Oh, sorry.

DR. HAYWOOD: I just want to quickly

comment that I want to heartily endorse the approach that's being taken here. The collection of ancillary death information is extremely important.

COL GARDNER: Absolutely.

MODERATOR FLETCHER: Thank you, Dr. Gardner.

EXECUTIVE SECRETARY FOGELMAN: Thank you.

(Applause.)

EXECUTIVE SECRETARY FOGELMAN: I need to make a few announcements before you break out. Also Dr. Weinstein has an announcement as well.

The subcommittee groups: the Infectious Disease Subcommittee, will be here. Health Maintenance will be in 3098, right next door. Environmental Occupational Health will be in 2133.

I'd also like to see a show of hands of the people that signed up to go out to dinner tonight and how many have cars. Could you please raise your hand?

(Whereupon, there was a show of hands.)

EXECUTIVE SECRETARY FOGELMAN: Five. I think we have enough cars. Okay. We'll say:

How does 6:00 o'clock in the lobby of the Malone House hotel sound? Okay? 6:00 o'clock.

You can probably stay here unless -- I don't know if there's somebody from WRAIR right here, but I think you could stay here up to about 5:30 probably if you need to. Does that sound reasonable? If you need to. We will meet again tomorrow morning starting at 8:00 o'clock. Great.

Now, I wanted to ask you -- we have a lot on our plates for the subcommittees. If you prefer, we could meet at 7:30. Actually, that may not be such a bad idea. What do you think?

Well, 8:00 o'clock would be the presentation anyway. We're going to have one presentation in the morning. So if you want to meet earlier here with your subcommittee, that's fine. But we'll start at 8:00 o'clock.

Dr. Weinstein?

DR. WEINSTEIN: The Health Maintenance Subcommittee will be taking up a series of recommendations concerning alcohol abuse prevention. We hope to bring them from the committee to the full Board tomorrow.

The draft of those statements is about five text pages. And you don't want to hear me

read through them tomorrow. So we would appreciate it if you would just look over those five pages before tomorrow's meeting.

MODERATOR FLETCHER: No other questions or comments before we --

EXECUTIVE SECRETARY FOGELMAN: So 6:00 o'clock in the lobby of the Malone House. It's going to be informal. So please dress informally.

(Whereupon, the foregoing matter was concluded at 1406 p.m.)